COMORBIDITY AND SYMPTOM MEASUREMENT IN ONCOLOGY SCALE: DEVELOPMENT AND PILOT RESULTS IN OLDER ADULT CANCER SURVIVORS

by

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ABSTRACT

More than two thirds of all cancers are diagnosed in older adults and the diagnosis often co-occurs with normal and pathological changes of aging, which include chronic diseases and related symptoms. The purpose of this measurement study was to conduct initial psychometric testing of a newly developed self-report tool to assess comorbidity burden and symptoms, the Comorbidity and Symptom Measurement in Oncology Scale (COSMOS), and to examine the feasibility of utilizing it with older cancer survivors. Phase 1 of the two-phase design focused on determining content validity using a panel of six expert clinicians and researchers. Each subscale item was evaluated for interrater agreement of relevancy using the content validity index (CVI). The scale-CVI was .80 for the comorbidity burden subscale (CoB) and .98 for the symptom perception subscale (SxP). The intraclass correlation coefficient (ICC) for each subscale was .97 (CoB) and .84 (SxP), respectively. Subscale items with a CVI of $\geq$.83 and ICC $\geq$.60 were retained. Phase 2 included pilot testing the revised CoB and SxP subscales and symptom attribution descriptor scale in a convenience sample of 62 older adult cancer survivors (32 on active treatment and 30 off treatment for 1 or more years). Although CoB scores were equivalent between groups, off-treatment group participants had significantly more thyroid and other miscellaneous conditions. SxP scores were also similar between groups; however, the active-treatment group reported significantly more nausea ($\chi^2 = 4.03$, $p = .045$), taste changes ($\chi^2 = 7.65$, $p = .006$), and body image disturbances ($\chi^2 = 6.44$, $p =$

.011) than the off-treatment group. Three clinically relevant symptom-attribution descriptors discriminated between treatment status groups, indicating a shift from aging and cancer-related attributions in those on active treatment to aging and other causes in the off-treatment population. Test-retest reliability indicated strong stability for comorbidity burden (ICC = .917) and symptom attribution (ICC = .696). COSMOS was judged to be a feasible measure based on subsample interviews, completion time, and response patterns. The results of this study support initial validity, reliability, and usability of COSMOS.

TABLE OF CONTENTS

ABSTRACT iii

LIST OF FIGURES ix

LIST OF TABLES x

LIST OF ACRONYMS AND ABBREVIATIONS xii

ACKNOWLEDGEMENTS xiv

Chapters

1 INTRODUCTION 1

Overview 1
Purpose and Aims 3
Significance 4
Summary 6
References 7

2 REVIEW OF THE LITERATURE 9

Background 9
Comorbidity and Cancer 9
Comorbidity Measurement in the Geriatric Oncology Population 11
Cancer-Related Symptoms in the Geriatric Oncology Population 12
Measurement of Cancer-Related Symptoms 16
Symptom Interpretation 22
Cancer-Related Symptom Appraisal of Older Adults 24
Comorbidity and Symptoms 26
Conceptual Framework 27
Summary 28
References 30

3 METHODS 36

Scale Development 36

Research Design and Methods 38
Overview of Design 38
Description of Instrument 39
Phase 1: Determining Content Validity 42
Sample 42
Instrumentation 42
Procedure 44
Data Analysis 46
Pilot Test of COSMOS 48
Sample and Setting 48
Power Analysis 49
Instrumentation 53
Procedure 55
Data Analysis 56
References 60

4 SYMPTOM EXPERIENCE AND CHRONIC ILLNESS IN OLDER ADULT CANCER SURVIVORS: AN EVIDENCE-BASED REVIEW 63

Abstract 63
Introduction 64
Methods 66
Definitions 67
Search Strategy 67
Results and Discussion 68
Influence of Chronic Illness on Symptom Experience in Older Adults With Cancer 82
Measurement of Symptoms 83
Measurement of Comorbidity 87
Conceptual Frameworks Related to Cancer Symptom Research 89
Limitations 92
Conclusions 92
Implications for Interprofessional Care and Research 94
References 96

5 DEVELOPMENT OF A SELF-REPORT TOOL FOR MEASURING COMORBIDITY BURDEN AND SYMPTOM PERCEPTION IN OLDER ADULTS WITH CANCER 101

Abstract 101
Introduction 102
Purpose 103
Background 104
Methods 107
Overview of Scale Development 107
Developmental Stage 108

Judgment-Quantification Stage....113
Results....116
Comorbidity Burden Subscale....117
Symptom Perception Subscale....117
General Scale Revisions....120
Discussion....120
Comorbidity Burden Subscale....121
Symptom Perception Subscale....122
Initial Scoring Guidelines....122
Limitations....123
Implications....125
References....126

6 COMORBIDITY AND SYMPTOM MEASUREMENT IN ONCOLOGY SCALE: INITIAL PSYCHOMETRIC RESULTS....131

Abstract....131
Introduction....132
Measurement of Comorbidities and Symptoms in Cancer Survivors....134
Methods....137
Participants....137
Instrumentation....139
Procedure....141
Statistical Analysis....142
Results....144
Feasibility....147
Comorbidity and Symptoms....148
Symptom Attribution....156
Relationship of Comorbidity Burden, Symptom Perception, and General Functioning....160
Reliability....160
Feasibility....162
Discussion....162
Construct Validity....162
Exploratory Relationships Between Key Variables....166
Reliability....167
Subscale Revisions....168
Limitations....171
Implications for Practice and Research....175
References....177

7 CONCLUSIONS AND RECOMMENDATIONS....182

Study Summary....182
Study Aims and Significance....185
Scale Development and Content Validity....185

Description of Instrument 187
Evidence of Construct Validity 188
Reliability 190
Summary of Pilot Results 191
COSMOS v2 Revisions 194
Limitations 195
Sample Size 195
Population Demographics 195
Time-Frame Reference for Assessment 196
Recruitment Challenges 197
Patient-Specific Treatment Variability 197
Frailty 198
Multiple Statistical Tests 199
Implications 199
Clinical Practice 199
Research 201
Education 203
Health Care Policy 205
References 207

Appendices

A: COSMOS VERSION 1 211

B: EXPERT PANEL RECRUITMENT LETTER 224

C: EXPERT PANEL REVIEW PACKET 226

D: COSMOS VERSION 2 248

E: GENERAL INFORMATION QUESTIONNAIRES 270

F: SAMPLE QUESTIONS FOR SEMISTRUCTURED INTERVIEW 276

G: PARTICIPANT RECRUITMENT LETTER 278

H: PARTICIPANT LETTER FOR TEST-RETEST PACKET 280

I: COSMOS VERSION 3 282

LIST OF FIGURES

Figures

2.1 Blended model of Theory of Unpleasant Symptoms and Common Sense Model 29

3.1 Study schema 40

4.1 Flow chart depicting results of the literature search strategy 69

5.1 Relationship of COSMOS and Conceptual Model 105

5.2 Comorbidity burden subscale, revised format 122

5.3 Symptom perception subscale, revised format 123

6.1 Example of revised comorbidity burden subscale item: Arthritis 171

6.2 Example of revised symptom burden subscale item: Fatigue.....172

7.1 Proposed integration of comprehensive geriatric assessment, COSMOS subscales, and phases of cancer survivorship 202

LIST OF TABLES

Tables

2.1 Select Comorbidity Assessment Tools 13

2.2 Select Cancer-Related Symptom Assessment Tools 17

2.3 Items in Select Cancer-Related Symptom Checklists 19

3.1 Scoring Guidelines for COSMOS 43

3.2 Rating New Item Relevancy 44

3.3 Data Used in the Calculation of Effect Size 52

4.1 Table of Evidence: Symptom Experience and Comorbidity in Older Adults With Cancer—Given-Kurtz Studies 71

4.2 Table of Evidence: Symptom Experience and Comorbidity in Older Adults With Cancer 75

4.3 Symptom Measures Used in Studies of Older Adult Cancer Survivors 84

5.1 Select Measurement Scales for Comorbidity in Oncology Populations 109

5.2 Select Measurement Scales for Symptoms in Oncology Populations 111

5.3 Rating New Item Relevancy 114

5.4 Content Validity for Single Items Within the Comorbidity Burden Subscale 118

5.5 Content Validity for Single Items Within the Symptom Perception Subscale 119

6.1 Summary of Participant Characteristics 145

6.2 Summary of Cancer-Related Participant Data 146

6.3 COSMOS Completion Time (Minutes)—Participant Self-Reported 147

6.4 Key Findings From Participant Interviews Regarding Symptom Appraisal 149

6.5 Reported Chronic Illnesses or Conditions by Participant Groups 150

6.6 Reported Symptoms by Participant Groups.....152

6.7 Relationships Between Similar Items on the Comorbidity Burden Subscale and the Symptom Perception Subscale.....155

6.8 Attributions for Most Frequently Reported Symptoms by >40% of the Study Sample.....157

6.9 Other Attributions for Selected Frequently Reported Symptoms.....159

6.10 Descriptive Data for Comorbidity, Symptoms, and Physical Function.....161

6.11 Correlations of Key Exploratory Variables (Pearson's *r* Statistic).....161

6.12 Revised Comorbidity Burden Subscale Items 170

LIST OF ACRONYMS AND ABBREVIATIONS

CES-D	Center for Epidemiological Studies Depression Scale
CI	confidence interval
CIRS	Cumulative Illness Rating Scale
CoB	COSMOS comorbidity burden subscale
COPD	Chronic Obstructive Pulmonary Disease
COSMOS	Comorbidity and Symptom Measurement in Oncology Scale
CSM	Common Sense Model
CSS	Comorbidity Symptom Scale
CVI	content validity index
FACT-G	Functional Assessment of Cancer Therapy–General
GIQ	general information questionnaire
ICC	intraclass correlation coefficient
IOM	Institute of Medicine
MMSE	Mini Mental Status Exam
MSAS	Memorial Symptom Assessment Scale
MSAS-SF	Memorial Symptom Assessment Scale–Short Form
NCI	National Cancer Institute
NIH	National Institutes of Health
OARS	Older American Resource and Service Schedule of Illnesses
PFI	pain, fatigue, and insomnia

PI	principal investigator
PROMIS	Patient-Reported Outcomes Measurement Information System
SEM	Symptom Experience Model
SxP	COSMOS symptom perception subscale
TOUS	Theory of Unpleasant Symptoms
UAMC	University of Arizona Medical Center

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CHAPTER 1

INTRODUCTION

Overview

Older adults comprise one of the most vulnerable and rapidly growing populations with cancer. Approximately 77% of all cancers are diagnosed in individuals 55 years and older, and the diagnosis often co-occurs with the normal and pathological changes of aging, which include chronic diseases and conditions (Howlader et al., 2015). The average number of comorbidities in the geriatric oncology population increases with age and ranges from two to four comorbidities (Cohen, Lan, Archer, & Kornblith, 2012; Deimling, Sterns, Bowman, & Kahana, 2005). The most prevalent chronic diseases and conditions in geriatric cancer patients include hypertension, cardiovascular conditions, arthritis, diabetes, and chronic lung disease, including asthma and chronic obstructive pulmonary disease (Bellury et al., 2012; Bender et al., 2008; Cohen et al., 2012; Grov, Fossa, & Dahl, 2011). Comorbidities and their symptoms may be associated with many adverse health outcomes, including the development of additional health problems, functional impairment and decreased mobility, increased hospitalizations, and the development of psychological symptoms such as anxiety and depression (Bellury et al., 2013; Deckx et al., 2012). The presence of comorbidities may have a profound effect on treatment outcomes, symptom management, and overall quality of life of older adults

with cancer, yet little is known about the impact of comorbidities in this population.

The "normal" symptom experience for the older adult population has a vague definition and may be related to the presence of comorbid conditions. It has been suggested that the traditional retirement age may be a developmental marker for changes in perception of discomfort, from abnormal to a normal expectation that comes with age (Williamson & Schulz, 1995). In addition, the perception of cancer-related symptoms may be impacted by beliefs of the expectations of normal aging or by the symptoms of other health problems (Mao et al., 2007. These phenomena may begin to explain the difference in symptom perception between younger adults and geriatric populations.

Historically, studies have suggested that older adults experience less severe cancer-related symptoms than younger adults, and that these symptoms generally cause more distress in younger populations when compared to older adults (Degner & Sloan, 1995; Williamson & Schulz, 1995). Cheung, Le, Gagliese, and Zimmerman (2011) studied 1,358 advanced-cancer survivors in the outpatient care setting to determine age and gender differences in reported symptom intensity. The results of the study suggest that cancer survivors aged 61 years and older did not experience a clinically significant difference in symptom severity and distress when compared to cancer survivors who were age 60 years and younger. The literature also suggests that physical symptoms and functioning are not directly related to age but rather to the comorbidities that may be present (Kolk, Hanewald, Schagen, & Gijsbers van Wijk, 2003; Kroenke, 2001). In addition, several studies have begun to associate comorbidity with increased symptoms and decreased functioning (Bellury et al., 2013; Bennett, Stewart, Kayser-Jones, & Glaser, 2002; Given, Given, Azzouz, & Stommel, 2001). Currently, there are few tools

available to measure an individual's symptom attribution related to comorbidities or other health-related problems.

Older adults with cancer may have an altered symptom perception due to their experience with co-occurring comorbidities. Altered symptom perception may affect "normal signals" to seek treatment if symptoms are perceived to be part of the aging process or due to comorbidities. Although studies have shown that an increased number of comorbidities is associated with increased symptoms, the phenomenon of symptom perception for the older adult with cancer and multiple comorbidities has been minimally explored (Bellury et al., 2012; Loerzel, 2015; Spoelstra et al., 2015). A critical evaluation of the literature on cancer and comorbidity, measurement of comorbidity, cancer-related symptom measurement, and symptom appraisal revealed minimal valid and reliable self-report tools to measure comorbidity burden, symptom burden, and symptom attribution.

This literature review provided a basis for the development and preliminary content validity of the Comorbidity and Symptom Measurement in Oncology Scale (COSMOS). The development and validation of a self-report, user-friendly measurement tool for comorbidity and symptom burden will contribute valuable information to the comprehensive geriatric assessment of older adults with cancer. This tool may provide insight into the impact of comorbidity on perceived symptom burden and lay a foundation for focused geriatric symptom assessment and subsequent studies of tailored interventions for symptom management and outcome measurement in this population.

Purpose and Aims

The broad goal of this study was to assess the psychometric properties of a self-report tool for measuring comorbidity burden and symptom perception that can be used

in the clinical setting as an integral component of the comprehensive geriatric assessment of older adults with cancer. The purpose of this methodological study was to conduct initial psychometric testing of COSMOS and examine the feasibility of utilizing it with older adults with cancer and comorbidities. The specific aims of the study included the following:

Aim 1.0: Determine the content validity of the Comorbidity and Symptom Measurement in Oncology Scale (COSMOS) by utilizing a survey method that includes both quantitative and qualitative data collection from a panel of expert clinicians/researchers in oncology, gerontology, geriatric oncology, and symptom assessment and management.

Aim 2.0: Determine the construct validity of the COSMOS by utilizing a mixed-method approach with a group of older adults with cancer.

Aim 3.0: Determine initial test-retest reliability of the COSMOS in a group of older adult cancer survivors who have finished active cancer treatment.

Aim 4.0: Determine the feasibility of a self-administered measurement tool of comorbidities and symptoms in a population of older adults with cancer, including tool completion time, response patterns, tool comprehension, missing items, and patterns in missing data.

Aim 5.0: Explore the sensitivity of the COSMOS between known groups of older adults on active cancer treatment and off treatment.

Secondary Aim: Explore the relationship of comorbidities, symptoms, and general functioning.

Significance

The role of comorbidity may be a significant factor in symptom perception and the impact of symptoms on the physical, psychological, and spiritual functioning of older adult cancer survivors in all phases of the cancer disease trajectory. In addition, it is essential to understand the impact of the normal aging process on the perception of cancer-related symptoms and optimal symptom control. Older adults with cancer may attribute their symptoms to the normal physiological changes associated with aging or

with comorbidities, yet little is known about this important aspect of symptom perception. The attribution of symptoms to expected and accepted physiological consequences of aging may lead to a delay in recognizing or failure to recognize cancer-related symptoms, which may have a negative impact on treatment outcomes and cancer survivorship.

Currently, there are minimal tools available to assess the phenomenon of symptom attribution in the older adult cancer population with comorbidities. Attribution is important, as it may guide the selection of an optimal intervention. The COSMOS may contribute essential information to the overall understanding of the impact of comorbidity and aging on the perception of symptoms in older adults with cancer. It is anticipated that this instrument will be a valuable assessment tool for oncology clinicians to use in the assessment and treatment of complex symptom constellations in the geriatric oncology patient. In addition, the COSMOS may provide clinical researchers with a unique tool for gathering further information about comorbidity burden and symptom attribution in older adult cancer survivors to assist in understanding this phenomenon and answer such questions as: Are specific comorbidities linked to specific symptoms as perceived by older adults with cancer? How does experience with comorbidity frame the symptom experience? How do comorbidity burden and symptom perception impact the diagnosis and treatment of cancer in older adults? This information can also be used to formulate and test tailored interventions for this vulnerable clinical population. In addition, the information gained from the COSMOS may be utilized to enhance targeted cancer education for the older adult population.

The key to successful health care management of this population is a

comprehensive geriatric assessment that includes physical, psychological, and functional status; comorbidity; socioeconomic status; nutrition; polypharmacy; and geriatric syndromes (Mohile & Magnuson, 2013). Establishing a valid, reliable, self-administered tool such as the COSMOS will make a valuable contribution to comprehensive geriatric assessment in the cancer population and guide the development of complex, multidisciplinary, evidence-based treatment plans for older adults with cancer.

Summary

This chapter addresses an overview of the clinical phenomenon to be studied and its significance to patient-centered care and optimal care management by an interprofessional team. In addition, the purpose and aims of the study are outlined in this chapter. Chapter 2 reviews the current relevant literature on chronic illness and cancer, cancer-related symptoms, measurement of comorbidity and cancer-related symptoms, symptom interpretation, and a conceptual framework that illustrates the potential relationships between symptoms, chronic illness, and relevant variables within the cancer survivor population. Chapter 3 outlines study methodologies used for instrument development, administration, and evaluation. Chapters 4 through 6 are prepared as articles intended for publication. Chapter 4 is a literature synthesis that reviews the current evidence on the relationship between comorbidity and symptoms in older adults with cancer. Chapter 5 reviews the development of a new measure for comorbidity burden and symptom perception. Chapter 6 reviews initial psychometric data and the findings of the instrument pilot study. Finally, Chapter 7 summarizes the study results, outlines limitations, and reviews the implications of this study for clinical practice, education, clinical research, and health care policy.

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CHAPTER 2

REVIEW OF THE LITERATURE

This chapter includes a review of background information that is foundational for the development of the Comorbidity and Symptom Measurement in Oncology Scale (COSMOS) and the interpretation of study results. Relevant literature in the content areas of comorbidity and cancer, cancer-related symptoms, measurement of both comorbidity and cancer-related symptoms, and the relationship between comorbidity and symptoms is reviewed. In addition, a discussion of a conceptual model that blends the Theory of Unpleasant Symptoms and the Common Sense model is included as the theoretical foundation for the COSMOS.

Background

Comorbidity and Cancer

There is a growing body of literature addressing the effects of comorbidity on cancer diagnosis and treatment, cancer-related treatment outcomes such as quality of life, and symptom assessment and management in older adults. The effects of comorbidity on cancer was one of several areas of research focus, as identified by the report from the workshop *Exploring the Role of Cancer Centers for Integrating Aging and Cancer Research*, which was jointly sponsored by the National Institute on Aging and the National Cancer Institute (NCI) in 2001. In this report, research priorities in comorbidity

and cancer were identified as (a) the development of a valid comorbidity assessment tool that is easy to administer, has minimal patient burden, is culturally sensitive, and is economical to administer; (b) exploration of the impact of comorbidity on patient care and outcomes of care; and (c) development of predictive models for individualized decision making regarding treatment (NCI, 2002). The overall goal of these priorities was to develop valid and reliable clinical assessment methods for comorbidity in older adults with cancer. The report offered suggestions for implementation of the research priorities, including developing a tool based on conceptual and clinically relevant information and pilot testing newly developed instruments to establish psychometric data. The development of a comprehensive self-report tool that measures comorbidity, symptom burden, and symptom attributions will facilitate understanding of the complexities of older adults with cancer, comorbidities, and symptoms, and planning and evaluating treatment outcomes for this population.

In 2012, the Institute of Medicine (IOM) published a report entitled *Living Well with Chronic Illness: A Call for Public Health Action*, which defined a chronic illness as "a condition that is slow in progression, long in duration, and void of spontaneous resolution, and it often limits the function, productivity, and quality of life of someone who lives with it" (IOM, 2012, p. 20.). In addition, the report discussed the concept of multiple chronic conditions as two or more chronic illnesses that affect one in four Americans. Cancer is identified in the report as one of the chronic illnesses that has a major impact on health and wellness beyond the initial treatment phase due to age, chronic symptoms, multiple chronic conditions, and functional limitations and decline.

Comorbidity, cancer, and functional status have been found to be significantly

related. Physical functioning in older adults with cancer has been found to be inversely correlated with comorbidity, and symptom severity was positively correlated with comorbidity (Kurtz, Kurtz, Stommel, Given, & Given, 2001). In addition, comorbidity has been found to be related to age and perceived activity restriction in cancer patients (Willliamson & Shultz, 1995), and to be an independent predictor of functional limitations in the older adult with cancer (Garman, Pieper, Seo, & Cohen, 2003; Vaeth, Satariano, & Ragland, 2000). Health care providers must be aware of the normal aging process and typical comorbid conditions in older adults and integrate this knowledge into geriatric oncology care.

Comorbidity Measurement in the Geriatric Oncology Population

There are several valid and reliable tools for measuring comorbidity that are constructed for use with a comprehensive review of the medical chart. Tools commonly used to assess comorbidity include the Charlson Index, Cumulative Illness Rating Scale–Geriatric, Kaplan–Feinstein Index, and Index of Coexisting Disease (De Groot, Beckerman, Lankhorst, & Bouter, 2003; Extermann, 2000). The Charlson Comorbidity Index is the most widely used measure of comorbidity; it rates 19 diseases with a weighted scoring system (1–6 points) that can be adjusted for age and was developed as a predictive tool for 1-year mortality among medical patients (Charlson, Pompei, Ales, & MacKenzie, 1987; Charlson, Szatrowski, Peterson, & Gold, 1994). The Charlson Comorbidity Index is used as the "gold standard" of comorbidity measurement; its content validity has been determined over 15 years of use with a wide variety of populations. In addition, it is a reliable measure with a test-retest reliability of $r = .91$ ($p = .0001$). One of the limitations of the Charlson Comorbidity Index is that it requires a

trained data collector to extract appropriate information from the medical record and code the data. In addition to issues with inaccurate data in the medical record, the use of this tool is not practical for the clinician and can be costly for researchers to use.

A self-report questionnaire version of the Charlson Index was developed by Katz, Chang, Sandha, Fossel, and Bates (1996). This tool is comprised of 10 main disease-oriented questions and several subquestions that assess the presence and severity of common comorbidities in older adults. This questionnaire was tested on 170 medical–surgical inpatients who were 55% female with an average age of 65.3 years; about 13% had a cancer diagnosis. Criterion-related validity results were at a moderate level (Spearman correlation = .63; $p = .0001$) with the Charlson Index, and test-retest reliability was high ($r = .91$; $p = .0001$). The authors identified a potential concern about accuracy of the self-report in the lower literacy population (Katz et al., 1996). Currently, there are minimal comprehensive self-report measurement tools for comorbidity burden. This type of tool has the potential to help clinicians as they formulate a treatment plan based on comprehensive patient data. Table 2.1 contains a summary of select comorbidity assessment tools.

Cancer-Related Symptoms in the Geriatric Oncology Population

Cancer-related symptoms, including the symptoms of pain, fatigue, nausea and vomiting, dyspnea, and depression, have been studied for more than 20 years in a wide variety of patients and diagnoses, but very few studies have been specifically focused on the older adult population. A small body of research-based evidence is beginning to identify inpatients and outpatients aged 27 to 89 years (mean age = 65.7 $\pm$ 11.9 years) with unique cancer-related symptoms in the geriatric population, the interrelationship of

Table 2.1

Select Comorbidity Assessment Tools

Symptom Measure	Description	Validity & Reliability	References
Charlson Index Predicts mortality risk over a period of a few weeks to 10 years from a broad range of diagnoses Adaptation also predicts mortality, length of stay, resource utilization, and length of stay	Rates 19 diseases with a weighted scoring system (1–6 points) * Adaptation for use with large data bases Type: Medical record data collection Uses: Multiple diagnoses	Content validity: Established over 15 years of use * Used as the "gold standard" of comorbidity measurement Test-retest reliability: *r* = .92 Interrater reliability: *r* = .74	Charlson, Pompei, Ales, & MacKenzie, 1987 Charlson, Szatrowski, Peterson, & Gold, 1994
Cumulative Illness Rating Scale (CIRS) – Geriatric Measures total disease burden and severity	Rates 14 body systems with weighted scoring system (0 = no impairment to 4 = life threatening) on a 7-point Likert-type scale Type: Medical record data collection Uses: Multiple diagnoses; specifically tailored for the geriatric population	Content validity: Based on existing CIRS–General, which has established validity and reliability Concurrent validity: Older Americans Activities of Daily Living Scale and Charlson Index (*r* = .39) Interrater reliability: *r* = .78 - .88	Extermann, Overcash, Lyman, Parr, & Balducci, 1998 Guralnik, 1996 Miller et al., 1992
Disease Count Measures the number of diseases present	Comorbidities are counted and totaled Type: Medical record data collection Uses: Multiple diagnoses and age groups	Content validity: Dependent on list of comorbidities used Reliability: Not reported	Melfi, Holleman, Arthur, & Katz, 1995 Vaeth, Satariano, & Ragland, 2000
Index of Coexistent Disease Measures the burden of current and chronic illnesses in the older adult	Rates 13 categories of comorbid diseases with two different dimensions * Index of Disease Severity (Grade 0 = no coexistent disease to Grade 3 = uncontrolled disease that causes moderate to severe disease symptoms) * Functional Severity (Level 0 = normal function to Level 2 = serious impairment) * Scores based on an	Content validity: Literature, clinical experience Concurrent validity: Disability scale of Older Americans Activities of Daily Living Scale Interrater reliability: Kappa = .5–.6 -Disease Severity subindex: Kappa = .4–.5 -Functional Severity subindex: Kappa = .6–.10 Intrarater reliability: Kappa = .9	Imamura, McKinnon, Middleton, & Black, 1997

Table 2.1 (Continued)

Symptom Measure	Description	Validity & Reliability	References
Index of Coexistent Disease (continued)	explicit list of symptoms, signs, and laboratory tests Type: Medical record data collection Uses: Multiple diagnoses; orthopedic patients		
Life Threat Risk Scale Measures potential impact of comorbid conditions on short-term survival of the individual	Classifies 35 comorbidities as absent, active, or past history Conditions are rated on a 0–3 scale (0 = negligible to 3 = high) Type: Medical record data collection Uses: Cancer patients	Content validity: List of comorbid conditions from National Institute on Aging and National Cancer Institute Convergent validity: Mortality statistics Reliability: Not reported	Yancik et al., 1996 Yancik & Wesley, 1998
Medication Count Measures the number of medications in specific disease categories	Evaluates an individual's health based on long-term drug therapy Type: Medical record data collection, self-report Uses: A wide variety of patient populations	Content validity: Dependent on list of drugs used and classifications Concurrent validity: Disease count	Glynn, Monane, Gurwitz, Choodnovskiy, & Avorn, 1999
Self-Report Questionnaire: Charlson Measures the presence of comorbid disease	Evaluates the presence of disease and in some diseases the severity of current comorbidities Uses a simple 10-item questionnaire with a combination of yes/no and multiple-choice questions Type: Self-report Uses: Older adult medical–surgical patients	Content validity: Charlson Index Criterion-related validity: Charlson Index $r = .63$ ($p = .0001$) Internal consistency: Cronbach's α = not reported Test-retest reliability: Intraclass correlation $r = .91$ ($p = .0001$)	Katz, Chang, Sandha, Fossel, & Bates, 1996

these symptoms, and their relationship with other variables unique to this population. Chang, Hwang, Feuerman, Kasimis, and Thaler (2000) studied symptom prevalence, intensity, and distress in 240 primarily genitourinary, lung, and hematologic cancers, as well as a variety of other cancers. The five most prevalent symptoms reported included lack of energy, pain, dry mouth, shortness of breath, and difficulty sleeping. On average, study participants reported 11–13 symptoms. Study results indicate that this population experienced a high prevalence of intense symptoms and suggested that pain and fatigue be considered a marker for the presence of other symptoms. This concept was later supported by Given, Given, Azzouz, Kozachik and Stommel (2001), who studied 841 patients aged 65 years and older with prostate, breast, lung, and colon cancers and found that the patients most likely to report pain and fatigue were those who had three or more comorbid conditions, lung cancer, and a later stage of disease.

Dodd, Miaskowski, and Paul (2001) explored the effect of a symptom cluster (pain, fatigue, and sleep insufficiency) on the functional status of 93 outpatients (mean age = 55.4 years) on chemotherapy at baseline and the end of the third cycle of chemotherapy. The symptoms of pain and fatigue contributed most as predictors of change in the patient's functional status. Similar results were obtained by Given, Given, Azzouz, and Stommel (2001), who studied 826 patients aged 72–75 years with breast, prostate, lung, or colon cancer at the beginning stages of treatment. They found that the symptom cluster of pain, fatigue, and insomnia was an independent predictor of a change in physical functioning unrelated to treatment or comorbid disease.

Overall, little is known about symptom experience of the geriatric oncology patient, including the severity of the symptom experience, the co-occurring multiple

symptoms, and the impact of these symptoms on function and quality of life. In addition, there is an emerging body of knowledge addressing the overall symptom experience in older adults as it relates to specific diagnoses, stage of disease, cancer-related treatments, disease progression, and comorbidities (Lacasse, 2016).

Measurement of Cancer-Related Symptoms

There are several valid and reliable measurement tools commonly reported in oncology symptom research, including the Symptom Distress Scale (Degner & Sloan, 1995; McCorkle & Young, 1978), the Edmonton Symptom Assessment Scale (Bruera, Kuehn, Miller, Selmser, & Macmillan, 1991), the Memorial Symptom Assessment Scale (Portenoy et al., 1994), the Rotterdam Symptom Checklist (de Haes, van Knippenberg & Neijt, 1990), and the M. D. Anderson Symptom Inventory (Cleeland et al., 2000). Table 2.2 provides a detailed description of these tools and their psychometric properties; a summary of the symptoms included in each tool is listed in Table 2.3.

Both the Memorial Symptom Assessment Scale–Short Form (MSAS-SF; Chang, Hwang, Feuerman, Kasimis, & Thaler, 2000) and the Rotterdam Symptom Checklist (de Haes et al., 1990) appear to have the most comprehensive list of symptoms that are congruent with the most common symptoms found in older adults with cancer (American Cancer Society, 2016). Both scales have good internal consistency and validity. The MSAS-SF appears to be commonly used in the United States to assess the presence and severity of cancer-related symptoms (Chang, Hwang, Feuerman, Kasimis, & Thaler, 2000). This tool measures the presence of 32 symptoms and their level of distress, if present.

The Memorial Symptom Assessment Scale–Short Form (MSAS-SF) has three

Table 2.2

Select Cancer-Related Symptom Assessment Tools

Symptom Measure	Description	Validity & Reliability	References
Edmonton Symptom Assessment Scale Measures symptoms of palliative care patients Estimated completion time: ~8 min.	Nine-item VAS (0–100mm) to measure current symptom levels * Numeric rating scale can be substituted Type: Self-report Population: Palliative care; medical oncology inpatients/outpatients—elder males with advanced disease	* Concurrent validity: RSCL, Brief Pain Inventory, MSAS, FACT-G * Convergent validity: KPS, inpatient status * Internal consistency: Cronbach's α = .79 * Test-retest reliability: 2 days = .86 (p<.0001); 1 week = .45 (p<.0001)	Bruera, Kuehn, Miller, Selmser, & Macmillan, 1991 Chang, Hwang, & Feuerman, 2000 Jenkins, Schulz, Hanson, & Bruera, 2000 Philip, Smith, Craft, & Lickiss, 1998
M. D. Anderson Symptom Inventory Assesses multiple cancer-related symptoms and their interference with various aspects of a patient's life in a 24-hour time period Estimated completion time: ~8 min.	Thirteen core items measured on presence and severity (0–10 scale) * Six-item symptom interference scale (0–10) Type: Self-report Population: Outpatients with multiple cancer types	* Content validity: Literature, clinical expertise * Concurrent validity: MSAS * Convergent validity: KPS, disease severity, number of symptoms * Internal consistency: Cronbach's α = .85 (general); Cronbach's α = .82 (gastrointestinal symptoms); Cronbach's α = .91 (interference)	Cleeland et al., 2000
Memorial Symptom Assessment Scale–Short Form (MSAS-SF) *MSAS (original): Assesses cancer-related symptom presence, frequency, severity, and distress over the previous week *MSAS-SF: Assesses symptom presence and distress on three subscales Estimated completion time: ~10 min.	Thirty-two items measured on 5-point Likert-type scale for symptom distress * Three subscales: High-prevalence physical symptoms; low-prevalence physical symptoms; psychological symptoms Type: Self-report Population: Clinical trials, epidemiology, inpatients/outpatients	* Content validity: MSAS * Concurrent validity: FACT- G * Convergent validity: KPS, extent of disease, inpatient status * Internal consistency: Cronbach's α = .80 global distress index; Cronbach's α = .82 physical distress index; Cronbach's α = .76 psychological distress index; Cronbach's α = .87 total MSAS * Test-retest reliability: 1 day r = .86–.94; 1 week r = .40–.84	Chang, Hwang, Feuerman, Kasimis, & Thaler, 2000 Chang et al., 1998 Portenoy et al., 1994
Rotterdam Symptom Checklist	A 31-item checklist that assesses symptom presence and bother	Content validity: Literature, clinical expertise, patient validation	de Haes, van Knippenberg, & Neijt, 1990

Table 2.2 (Continued)

Symptom Measure	Description	Validity & Reliability	References
Rotterdam Symptom Checklist (continued) Measures symptoms of individuals undergoing clinical trials Estimated completion time: ~8 min.	using a 4-point Likert-type scale (0 = not bothered at all to 4 = bothered very much) Type: Self-report Population: Clinical trials, active chemotherapy, advanced ovarian cancer, disease-free patients	Concurrent validity: Symptom Distress Scale Internal consistency: Cronbach's α = .88 (psychological scale) Cronbach's α = .82 (physical scale)	
Symptom Distress Scale Assesses the severity of multiple symptoms Estimated completion time: ~3 min.	Original tool had 10 items Thirteen items measured on a 5-point Likert-type scale for symptom distress Some revised versions use a 100mm visual analogue scale Type: Self-report Population: Multiple types of cancer patients	* Content validity: Literature; established with patients actively undergoing chemotherapy and radiation treatments for cancer * Convergent validity: Inventory of current concerns, Profile of Mood States subscales * Internal consistency: Cronbach's α = .78–.89 * Test-retest reliability: *r* = .78	Degner & Sloan, 1995 McCorkle & Benoliel, 1983 McCorkle & Young, 1978 Munkres, Oberst, & Hughes, 1992 Stapleton, Holden, Epstein, & Wilkie, 2015

Note. RSCL = Rotterdam Symptom Checklist; MSAS = Memorial Symptom Assessment Scale; FACT-G = Functional Assessment of Cancer Therapy–General; KPS = Karnofsky Performance Scale.

Table 2.3

Items in Select Cancer-Related Symptom Checklists

Edmonton Symptom Assessment Scale 9 Items	M. D. Anderson Symptom Inventory 15 Items	Memorial Symptom Assessment Scale– Short Form 32 Items	Rotterdam Symptom Checklist 31 Items	Symptom Distress Scale 13 Items
Activity	Distress	Changes in skin	Abdominal aches	Appearance
Anxiety	Disturbed sleep	Changes in taste	Anxiety	Appetite (degree)
Appetite	Drowsiness	Constipation	Burning or sore eyes	Bowel pattern
Depression	Dry mouth	Cough	Constipation	Breathing
Drowsiness	Emesis	Diarrhea	Decreased sexual interest	Concentration (degree)
Nausea	Fatigue	Difficulty concentrating	Depressed mood	Cough (degree)
Pain	Global interference	Difficulty swallowing	Desperate feeling about the future	Fatigue (degree)
Sensation of well-being	Global severity	Dizziness	Diarrhea	Insomnia (degree)
Shortness of breath	Lack of appetite	Does not look like self	Difficulty sleeping	Nausea (presence)
	Nausea	Dry mouth	Difficulty concentrating	Nausea (degree)
(Chang, Hwang,	Numbness and tingling	Feeling bloated	Dizziness	Outlook (degree)
Feuerman, & Kasimis,	Pain	Feeling drowsy	Dry mouth	Pain (presence)
2000; Jenkins, Schulz,	Remembering	Feeling irritable	Feeling lonely	Pain (degree)
Hanson, & Bruera, 2000;	Sad	Feeling nervous	Headaches	
Philip, Smith, Craft, &	Shortness of breath	Feeling sad	Heartburn/belching	(McCorkle & Benoliel,
Lickiss, 1998)		Feeling sleepy	Irritability	1983; McCorkle &
	Additional Items	Hair loss	Lack of appetite	Young, 1978)
	* BMT:	Itching	Lack of energy	
	Bleeding	Lack of appetite	Hair loss	
	Diarrhea	Lack of energy	Low back pain	
	Difficulty paying attention	Mouth sores	Nausea	
	Feeling physically sick	Nausea	Nervousness	
	Mouth sores	Numbness and tingling	Shivering	
	Weakness	Pain	Shortness of breath	
	* Gastrointestinal Cancer:	Changes in sexual interest	Sore mouth/pain when swallowing	
	Soreness at radiation site	Shortness of breath	Sore muscles	

Table 2.3 (Continued)

Edmonton Symptom Assessment Scale 9 Items	M. D. Anderson Symptom Inventory 15 Items	Memorial Symptom Assessment Scale– Short Form 32 Items	Rotterdam Symptom Checklist 31 Items	Symptom Distress Scale 13 Items
	Swallowing * Lung Cancer: Cough Sore throat (Cleeland et al., 2000)	Sweats Swelling of arms/legs Urination problems Vomiting Weight loss Worrying (Chang, Hwang, Feuerman, Kasimis, & Thaler, 2000; Chang et al., 1998)	Tension Tingling of hands/feet Tiredness Vomiting Worrying (de Haes, van Knippenberg, & Neijt, 1990)	

subscales, including a physical and psychological symptom scale and a global distress scale, and has been tested in oncology inpatient and outpatient populations. This tool has acceptable internal consistency reliability (Cronbach's $\alpha = .76–.87$), variable 1-week test-retest reliability (Pearson $r = .40–.84$), and convergent validity with the Functional Assessment of Cancer Therapy–General (FACT-G) tool. Few studies have explored the use of these tools in the geriatric oncology population, and there is little published research on measurement tools that assess older adults' appraisal of the origin of a particular symptom or group of symptoms.

Recently, the Patient-Reported Outcomes Measurement Information System (PROMIS) initiative developed standardized tools for measuring common patient-reported outcomes in health care (Cella et al., 2010). There are multiple PROMIS measures available for many outcomes related to symptoms commonly found in cancer-survivor populations, such as pain, fatigue, sexual function, sleep disturbance, anxiety, distress, sleep disturbance, gastrointestinal symptoms, dyspnea, and cognitive functioning. In addition, the Global Health Scale is a 10-item scale and assesses general health; quality of life; physical, mental, and social health; physical function; and three symptoms (pain, fatigue, and emotional symptoms; Hays, Bjorner, Revicki, Spritzer, & Cella, 2009). However, there is no global symptom assessment. Wagner et al. (2015) recently demonstrated the successful integration and use of select PROMIS symptom and physical-function measures into the electronic medical record to provide automated messages about symptoms of concern to appropriate members of the health care team.

Symptom Interpretation

An individual's interpretation of his or her symptoms can be comprehensively understood by using an information-processing model such as the Common Sense Model (CSM). This model proposes that people have specific ideas about their illnesses and that these ideas guide coping behaviors for health and illness (Ward, 1993). The CSM describes three stages of information processing, including cognitive and emotional representation of illness, coping with illness, and appraisal of the effectiveness of the coping strategy. The representation of symptoms includes the following characteristics of a symptom: identity, perceived cause, temporal nature, outcomes of disease related to the symptom, and ideas about potential treatments. The coping stage includes an individual's behavioral action based on the representation of the illness or symptom. The appraisal stage involves the individual's evaluation of the outcomes of the coping phase, which may change the person's representation or coping behaviors for the symptom. This general framework integrates the physical, psychological, and social dimensions of symptom perception and subsequent choices of symptom-management actions. It assists the clinician in understanding the complex nature of symptom interpretation and its potential impact on patient-care treatments and outcomes.

Understanding the subjective differences between the origins of symptoms in the older adult may be significant in the development and implementation of tailored interventions for symptom management in this population. The distinction between the disease process, treatment side effects, and the normal physiological changes of aging may guide individual health-behavior choices. Results of a study of HIV-positive individuals aged 31–65 years on highly active antiretroviral therapy suggest that patients

can make specific distinctions between identifiable causes of physiological symptoms of disease and treatment (Johnson, Stallworth, & Neilands, 2003). In addition, older adults may have a multidimensional representation of aging. Using the CSM framework, older adults with cancer and comorbidities use body sensations, past experiences of illnesses and symptoms, and related interactions with family, friends, and health care providers to make decisions about their symptoms. A study by Prohaska, Keller, Leventhal, and Leventhal (1987) revealed that mild symptoms of short or long duration are more likely to be attributed to aging than severe, short-term symptoms. In addition, the attribution of mild symptoms with gradual onset to aging resulted in a greater acceptance of symptoms with a subsequent delay in seeking health care for the symptoms (Prohaska et al., 1987). Little is known about older adults with cancer and comorbidities and their perception of symptoms and their related causes. Understanding symptom perception in older adults with cancer may lead to more timely diagnosis and treatment of disease and comprehensive symptom management.

Gender may also play an important part in the interpretation of symptoms of chronic and acute illnesses. The literature on cardiac patients suggests that men and women have different perceptions of cardiac-related symptoms. Granot, Ferber, and Azzam (2004) conducted a study of 61 adults (29 women, 32 men) with complaints of chest pain and a diagnosis of unstable angina to evaluate the multidimensional perception of the experience of chest pain symptoms between men and women. The mean age of the study population was 68.5 years. Structured interviews were conducted with study participants and results suggest that there are gender differences in the perception of the cause of chest pain, in reporting and describing pain, and in tolerance of pain. Women

tended not to attribute their chest pain to heart disease, and demonstrated more perceptual responses to pain by reporting more symptoms than men. In contrast, Jackson, Chamberlin, and Kroenke (2003) studied 528 people at a general-medicine walk-in clinic with a chief complaint of physical symptoms and found that there were no significant gender differences in symptom distribution, duration, and severity; however, women were more likely to report symptoms as currently bothersome.

Van Wijk, Huisman, and Kolk (1999) conducted a longitudinal study to explore the gender differences in daily symptom reporting by 153 participants (>50% women). They found significantly higher symptom reporting by women, and that illness behavior was strongly associated with the experience of physical symptoms. Finally, Hofman and colleagues (2004) studied the perception of expected side effects associated with cancer therapy in 938 cancer patients. Results indicate that the median number of side effects expected was nine and that women expected more side effects than men. An additional finding was that participants aged 60 and older expected fewer side effects than younger participants. In summary, it appears that there is a gender difference in symptom perception but it is unclear how this difference may be moderated by age and comorbidities.

Cancer-Related Symptom Appraisal in Older Adults

Some older adult patients may learn to cope with chronic symptoms (such as pain and fatigue) as a normal part of the aging process, have different expectations regarding functional ability compared to younger adults, perceive symptoms as age-related, and experience less symptom distress due to their frame of reference. McMillan (1989) studied the relationship between cancer-related symptom intensity and the age of 25

outpatients being treated for lung or breast cancer. Subjects were stratified into two age groups for comparison: those <55 years and those >56 years. Age and symptom severity were correlated and comparative results showed that younger patients reported a higher symptom severity than older patients. This study suggests that older patients experience physical symptoms with less intensity than younger patients; however, it is unknown whether this is due to a decreased overall symptom experience or an altered symptom perception by older patients (McMillan, 1989). The meaning of aging is very individual and has many dimensions that create an individual context for defining symptoms. Dimensions for ascribing meaning to symptoms experienced by older individuals include the unique individual, their life experiences, chronic conditions, and individual beliefs about quality of life.

Symptom perception is also multidimensional and incorporates gender and cultural perspectives, life experience and beliefs, and the overall meaning of a particular sensation (Teel, Meek, McNamara, & Watson, 1997). The life experience of an older adult with cancer is likely to include comorbidities that have an impact on the meaning of symptoms for the individual and his or her family. Literature suggests that comorbidities and symptoms within the oncology population may be predictors of overall prognoses and may have a major impact on treatment decisions and disease outcomes (Hall et al., 2002; Piccirillo & Feinstein, 1996; Repetto et al., 1998; Satariano & Ragland, 1994). Currently, there are few measures that examine comorbidity and symptom perception in cancer patients. The development of a tool that can be used by clinicians to identify the burden of comorbidity and coexisting symptom perception in older adults with cancer will assist clinicians in formulating appropriate treatment plans and assessing outcomes

among this population.

Comorbidity and Symptoms

Age has been linked to physical symptoms and comorbidities. Older age may be related to increased physical symptoms mediated by an increased number of chronic illnesses (Kolk, Hanewald, Schagen, & Gijsbers van Wijk, 2003). In addition, a study of advanced lung cancer survivors aged 65–89 with increased comorbidities found that the participants with increased comorbidities tended to report increased numbers of symptoms (Gift, Jablonski, Stommel, & Given, 2004). An interviewer-administered tool to measure comorbidities and their associated symptoms was developed by Crabtree, Gray, Hildreth, O'Connell, and Brown (2000). The Comorbidity Symptom Scale (CSS) was developed based on interview data that identified the most prevalent comorbidities found in older adults. The scale incorporates the presence of 23 comorbidities and the severity of their associated symptoms. Test-retest reliability in a group of cataract surgery patients aged 65–92 years was reported as $r = .87$ ($p<.001$). This scale allows the interviewer to obtain symptom data directly from the patient, but comorbidities might not be identified using this measure if there are no associated symptoms. In addition, the CSS has moderate concurrent validity with assessments of perceived health, anxiety and depression, and activities of daily living. This tool provides a general overview of comorbidity and specific symptoms, but does not allow for broad assessment of symptoms with multiple attributes such as disease, treatment, and aging. A further review of the literature that addresses the intersection between cancer, comorbidities, and symptoms can be found in Chapter 4.

Conceptual Framework

The Theory of Unpleasant Symptoms (TOUS) was used as the conceptual basis for the initial development of the COSMOS (Lenz, Pugh, Milligan, Gift, & Suppe, 1997; Lenz, Suppe, Gift, Pugh, & Milligan, 1995). This middle-range theory describes both the antecedents and sequelae of unpleasant symptoms such as cancer-related fatigue or pain. The model incorporates three factors that influence symptoms, including physiological, psychological, and situational factors. Physiological factors that may precede unpleasant symptoms include normal and altered body function or comorbidity, an individual's level of energy, and an individual's cellular response to healing. Psychological factors include the state of mental health, such as depression or anxiety, and the individual's reaction to illness. The situational factors include social support, living arrangements, and so forth. These three factors interact with each other and have a direct impact on the development and exacerbation of symptoms and an individual's symptom perception. Symptoms in this model are depicted as having four components: distress, duration, quality, and intensity. Symptoms are also thought to occur in groups or clusters, interact with each other, and ultimately affect an individual's functional status, cognitive functioning, and physical performance. The effect of symptoms on overall performance, in turn, has an adverse impact on the symptoms and factors that were antecedent to symptom development.

A blended conceptual model using the CSM of symptom perception and appraisal and the TOUS was used as a basis for the current study. The Perception of Unpleasant Symptoms model describes physiological, psychological, and situational factors as having an integrated effect on the cognitive and emotional representation of illness.

Perception of these factors influences overall symptom burden that affects the outcomes of the symptom experience and comorbidity management. In this study, this outcome was defined as *interference with functioning*. The impact of the perception of symptoms and comorbidities may affect both symptom burden and general functioning. Interference with functioning, in turn, has an effect on perception of symptoms and comorbidities. A depiction of this model is presented in Figure 2.1.

This model suggests that symptom-management interventions may be effective at the antecedent level to prevent or decrease the perception of symptoms and comorbidities and the subsequent development of symptoms that have an impact on functional performance (Lenz et al., 1997). The COSMOS may provide valuable insight into some of the antecedents to symptom development in the older adult and guide symptom-management interventions to increase performance that may be affected by symptoms. The presence of comorbidity in the older adult with cancer may lead to the development of complex symptoms, which may affect overall functioning and quality of life (Dodd et al., 2001; Gift et al., 2004).

Summary

This chapter summarizes a theoretical- and practice-based foundation for the development of a comprehensive clinical assessment tool for cancer survivors with multiple chronic illnesses and symptoms. In addition, classic measures for comorbidity and symptoms are discussed and analyzed.

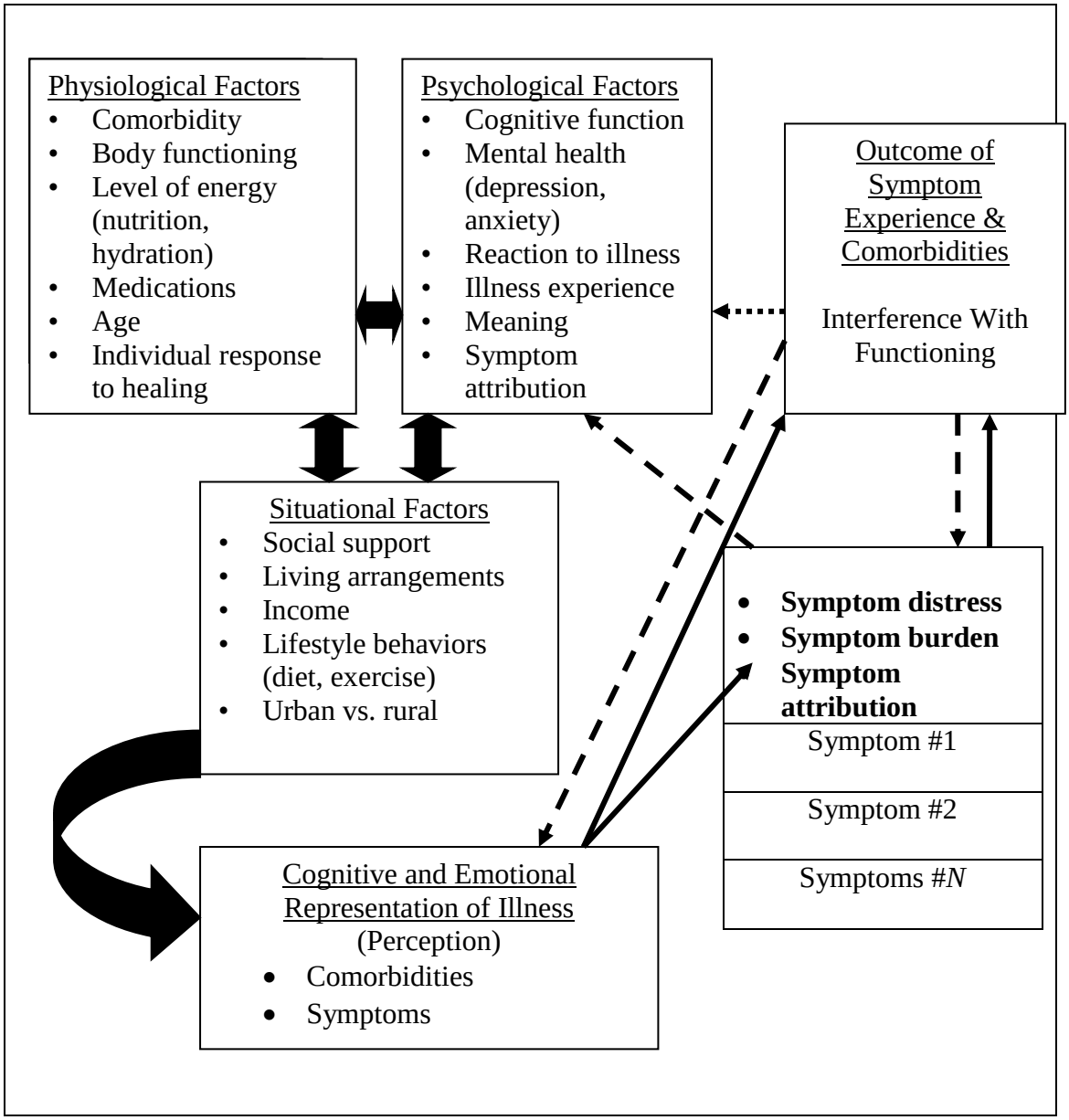

Figure 2.1 Blended model of Theory of Unpleasant Symptoms and Common Sense Model.

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CHAPTER 3

METHODS

Scale Development

The Comorbidity and Symptom Measurement in Oncology Scale (COSMOS) is a newly developed scale that measures comorbidity burden and symptom perception. COSMOS uniquely combines a self-report assessment of a broad range of comorbidities commonly found in older adults, such as arthritis and cardiovascular, renal, gastrointestinal, hepatic, endocrine, and neurological disease processes, with a comprehensive symptom perception assessment (Tabloski, 2014). The juxtaposition of reported comorbidities and symptom perception provides the older adult with an opportunity to consider symptoms within the context of her or his current health, inclusive of comorbidities, cancer diagnosis, treatment, and perceptions of the aging process. The scale may provide a unique view of the symptom experience of the older adult with cancer and lead to symptom-management guidelines tailored to the specific needs of older adults with cancer and comorbidities.

The COSMOS was developed for a target population of older adults (>65 years old) with cancer who have more than one comorbidity and more than one symptom. During construction of this new measure, specific physiological changes of aging were taken into account. such as fatigue from measurement burden, “test anxiety,” decreased

clarity of thought with complex concepts, and impaired vision (Burnside, Preski, & Hertz, 1998; Ingram et al., 2002; Rasin, 2004). The COSMOS has a simple construction, easy readability, and simple instructions. It is anticipated that the scale can be read easily with 12-point font and a high-contrast print of black lettering on a white background. The estimated time for completion of the scale is about 15 minutes, and it can be completed by a proxy respondent if the patient is unable to physically complete the scale. The COSMOS is a self-report scale and should be a valid and reliable measure of the patient's comorbidity burden and symptom perception (Ingram et al., 2002; Silliman & Lash, 1999; Tishelman, Taube, & Sachs, 1991). Subscales were developed based on simplicity and ease of use and include dichotomous, Likert-type, and categorical scales.

The major components of the scale are comorbidity burden and symptom perception. Comorbidity burden is defined as the presence of illness or chronic condition manifested over a lifetime or past year or month and its effect on daily life. Chronic conditions that may have acute exacerbations may be more sensitive to temporal changes and are assessed within a shorter timeframe to capture this phenomenon. Symptoms are defined as "subjective experiences reflecting changes in a person's biopsychosocial function, sensation, or cognition" (University of California, San Francisco School of Nursing Symptom Management Faculty Group, 1994, p. 273). Symptom perception has been defined as an individual's cognitive appraisal of a sensation or function within a multicontextual perspective (Teel, Meek, McNamara, & Watson, 1997). This study defines symptom perception to include symptom bother (how much a symptom bothers an individual). In addition, symptom attribution is defined as the individual's view of what might cause a specific symptom.

Research Design and Methods

Overview of Design

A crucial factor in instrument development is the assessment of content validity. The determination of content validity includes a two-stage process, as described by Lynn (1986). The first stage is described as the developmental stage, which incorporates identification of the content domain(s), comprehensive item generation, and construction of a useable format for generated items. Preliminary content validity for COSMOS was derived from a critical evaluation of the literature on the measurement of comorbidity, cancer and comorbidity, cancer-related symptom measurement, and symptom appraisal. The content of the comorbidity subscale was derived from a review of the literature on measurement of comorbidities and oncology-related studies that included symptom assessment and comorbidities. The symptom perception subscale is an adaptation of the Memorial Symptom Assessment Scale–Short Form (MSAS-SF), which is reported to have moderate-to-good validity and reliability in the older adult cancer population (Chang, Hwang, Feuerman, Kasimis, & Thaler, 2000). In addition, initial content validity of the symptom subscale was supported by reviewing a list of symptoms that accompany the most prevalent cancers within the older adult population (aged 60+ years), including lung, breast, prostate, colorectal, pancreatic, bladder, and ovarian cancers, and leukemia and non-Hodgkin's lymphoma (American Cancer Society, 2016).

This study was a continuation of the instrument development process and implemented Stage 2, which is the judgment-quantification stage. This stage included utilizing a panel of experts to determine the relevancy of each item in the instrument and the relevancy of the instrument as a whole. During this stage, expert feedback was used

to assess and shape a new instrument for pilot testing. The next step in the study was to complete the determination of content validity and perform initial testing of COSMOS in a population of older adults with cancer.

A mixed-method study design was used to conduct initial psychometric testing of COSMOS and examine its feasibility in measuring comorbidity and symptom perception in older adults with cancer. Initial content validity was determined by using a panel of six expert clinicians who had a working knowledge of oncology care, gerontology, or geriatric oncology care and symptom assessment and management. The original tool was revised based on the results of the expert panel critique and pilot tested with a population of older adults with cancer. A mixed-methods approach to data collection was used in both the initial determination of content validity and the pilot test of the instrument. Quantitative data were collected from the panel of experts regarding the relevance of comorbidity assessment questions and symptom perception scales. Qualitative data in the form of written comments were collected with regard to specific suggestions for revision of the original tool, including omission of critical comorbidity and symptom questions. During the pilot testing phase of the study, participants were asked to complete the revised tool and then were invited to comment on specific aspects of the tool. Purposeful revision of the tool was based on the pilot data. The study schema is shown in Figure 3.1.

Description of Instrument

The COSMOS (version 1) is a self-administered scale that measures comorbidity burden and multidimensional symptom perception in adults with cancer. The COSMOS includes the comorbidity burden subscale, the symptom perception subscale, and a symptom attribution descriptor scale.

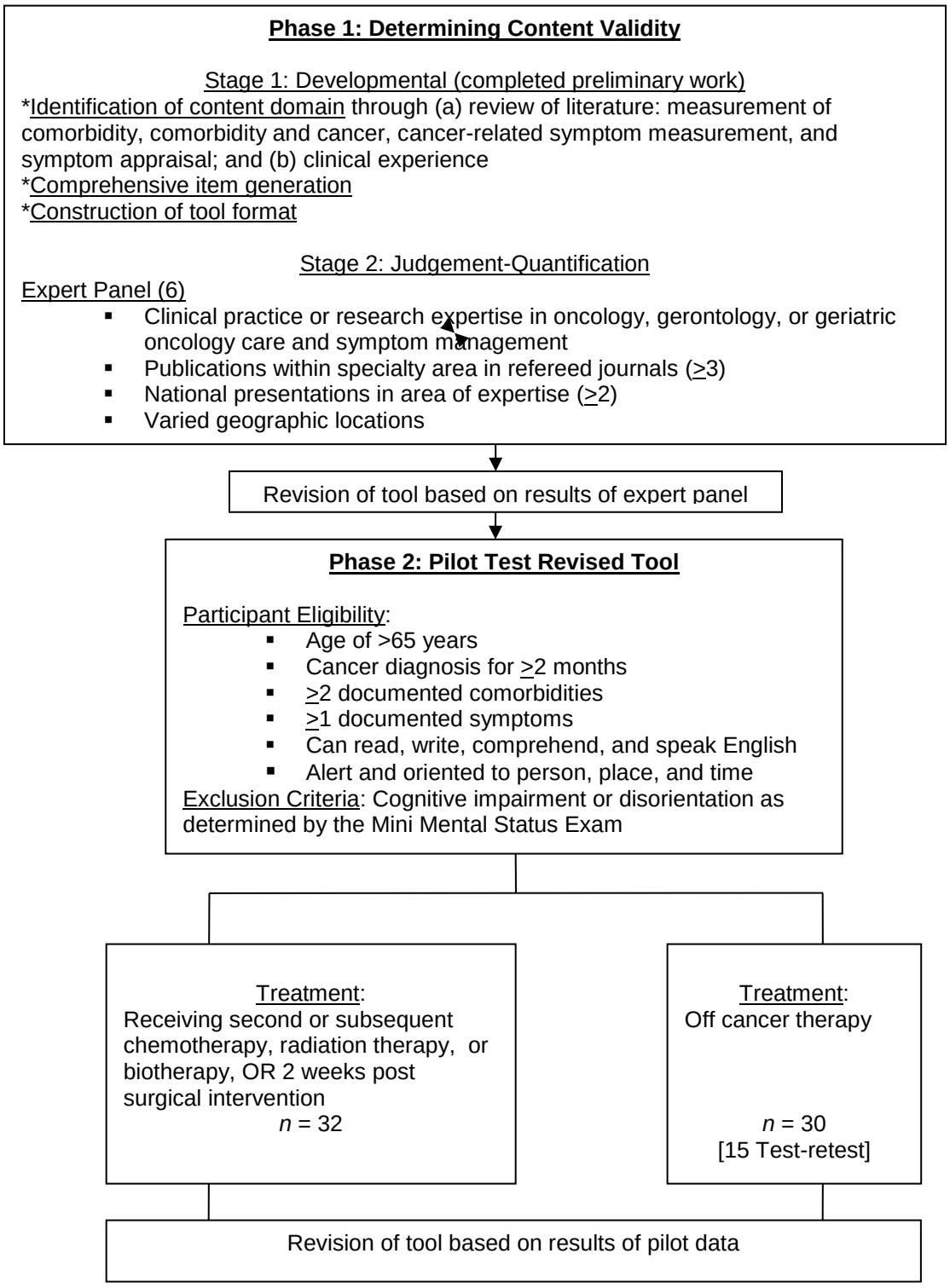

Figure 3.1 Study schema.

The comorbidity burden subscale combines a 38-item checklist comprised of yes/no questions that assess the presence of a comorbid disease and a four-point scale for rating the effect of the comorbidity on daily life. The scale has 32 items focused on physical conditions, four items focused on psychological conditions, and two chronic symptoms that can be defined as a chronic comorbidity (pain and fatigue). Overall readability of this subscale is a 7.1 grade level, as measured by the Flesch-Kincaid Readability Scale (Paz, Liu, Fongwa, Morales, & Hays, 2009).

The symptom perception subscale has three component scales, including the presence of physical and psychological symptom scale, the symptom bother scale, and the symptom attribution scale. The symptom presence subscale has 32 items (26 physical symptoms and six psychological symptoms). This scale is an adapted version of the MSAS-SF, which measures the presence of symptoms and their level of distress if present (Chang et al., 2000). The original MSAS-SF has been tested in oncology inpatient and outpatient populations and has established internal consistency reliability (Cronbach's $\alpha = .76–.87$), variable 1-week test-retest reliability (Pearson $r = .40–.84$), and convergent validity with the Functional Assessment of Cancer Therapy–General tool (Chang et al., 2000). The symptom bother subscale of the COSMOS is a three-point Likert-type scale designed to measure symptom distress; it was collapsed from the original five-point scale in the MSAS-SF. This scale was collapsed to facilitate the completion of the tool with minimal response burden for the older adult population. The symptom attribution subscale includes five descriptors designed to collect data on participants' perceptions about the cause of their symptom, including cancer, cancer treatment, aging, medications for noncancer conditions, and some other

explanation. In addition, there is a space for participants to add and evaluate other symptoms they are experiencing that are not on the list. Overall readability of this subscale is a 3.8 grade level as measured by the Flesch-Kincaid Readability Scale (Paz et al., 2009). Table 3.1 describes the scoring system for the COSMOS.

Phase 1: Determining Content Validity

Sample

A panel of 12 experts was invited to participate in the evaluation of the content of the scale. Seven expert clinicians/researchers agreed to participate; however, only 6 completed the survey within the study timeframe. Each participant met the following inclusion criteria:

- Clinical practice or research expertise in oncology, gerontology, or geriatric oncology care and symptom management
- Publications within specialty area in refereed journals (≥3 publications)
- National presentations in area of expertise (≥2 presentations)

Experts were identified through specialty-organization contacts and literature searches for publications listed in traditional health care literature databases. Every effort was made to recruit expert panelists from a variety of geographical areas in the United States.

Instrumentation

Expert Panel Tool-Critique Form

Each participant in the panel of experts received a copy of COSMOS version 1 (v1; Appendix A) and used a critique form to record item relevancy and overall instrument relevancy for COSMOS. A Likert scale was used for determining relevancy of the items, and the overall scale is as delineated by Lynn (1986; see Table 3.2). In

Table 3.1

Scoring Guidelines for COSMOS

Subscale	Description	Scale	Scoring
Comorbidity Presence ▪ Physical ▪ Psychological ▪ Chronic symptoms	Assesses the presence of comorbidity over a lifetime and previous year	Dichotomous Nominal	Yes = 1 No = 0 Total score: 0–38
Comorbidity Impact	Assesses the perceived effect of comorbidities on daily life	Likert Ordinal	Each comorbidity: 0 = "not at all" +1 = "a little" +2 = "some" +3 = "a great deal"
Comorbidity Burden	Assesses total burden of comorbidity on daily life	Continuous	Total comorbidities present plus comorbidity impact score Total score: 0–152
Symptom Perception: Presence ▪ Physical ▪ Psychological	Assesses the presence of symptoms over the previous month	Dichotomous Nominal	Yes = 1 No = 0 Physical: 0–26 Psychological: 0–6 Total score: 0–32
Symptom Perception: Distress	Measures the amount of symptom distress or bother experienced due to each symptom	Likert Ordinal	Each symptom: +0 = "none or a little" +1 = "some" +2 = "a great deal"
Total Symptom Perception Score	Assesses the total impact of symptoms	Continuous	Total symptoms present and symptom bother scores Total score: 0–96
Symptom Perception: Attribution	Describes the perceived origin of each symptom present	Nominal	Each symptom scored on each "attribute": aging, cancer, cancer treatment, medication for noncancer conditions, or other Attributes are used as descriptors for the patient's understanding of the symptom.

Table 3.2

Rating New Item Relevancy

4-Point Rating Scale for Describing Relevancy of Items and Scales	
Rating	Description
1	Not relevant
2	Unable to assess relevance without item revision, OR Item is in need of such revision that it would no longer be relevant
3	Relevant but needs minor alteration
4	Very relevant and succinct

Adapted from Lynn, 1986, p. 384.

addition, each expert panelist was asked to comment on specific aspects of the overall tool, such as clarity of instructions, time frames of patient experiences, critical omissions from each scale, suggestions for specific item revision, tool format, and general overall comments about the tool.

Procedure

I obtained initial approval for the study from the University of Utah Institutional Review Board and the Clinical Cancer Investigations Committee. Study approval was also obtained from University of Arizona Medical Center (UAMC), which provided access to all UAMC entities. Following approval, I identified potential expert panel participants according to the eligibility criteria stated above. Each potential expert panelist (N = 12) was contacted via email and invited to participate in the study by using a standardized letter explaining the purpose of the study, their role within the study, and the expected time frame of the study. The panel recruitment letter is shown in Appendix B. If the panelist agreed to participate within the specified time frame, an expert panel

packet was sent to them and they were given 4 weeks to return their responses about the scale; the packet included the following:

- An introduction letter to the study;
- A brief description of the scale, its content domains, the objectives for scale construction, and a definition of terms;
- Specific instructions and guidelines for study participation and data collection;
- A copy of COSMOS v1;
- A copy of the scale, with relevancy rating scale and comments fields for each item; and
- A self-addressed, stamped envelope for returning item ratings and comments.

The full expert panel packet is provided in Appendix C.

Participants were asked to rate each item to assess the relevancy of each item of the comorbidity burden subscale, symptom perception subscale, symptom attribution descriptors, and the entire tool. In addition, each panelist was asked to identify omissions from this subscale and comment on items that were identified as having minimal relevancy (those rated with a 1 or 2). In addition, each expert panelist was asked to comment on specific aspects of the overall tool, including clarity of instructions, overall format in relation to the target population, and any omissions from either subscale. Reminder emails were sent to the experts at 2 and 4 weeks after the initial packet mailing.

Item revisions were incorporated into the second version of the scale. Revision suggestions from the expert panel had strong agreement, and the process did not need to be repeated. Results are reported in Chapter 5.

Data Analysis

A detailed plan was developed for coding and building a database for quantitative data in SPSS 23.0® for Windows. All quantitative data were entered into one database by the PI and then compared with raw data for accuracy. Mismatched data were re-entered. Open-ended responses from the participants were carefully analyzed for specific suggestions for improvement by me.

Professional characteristics of the expert panel, such as number of years in nursing, number of years in specialty practice (oncology, gerontology, symptom management), and current professional position and responsibilities, were described using descriptive statistics, including frequencies for nominal data and measures of central tendency for continuous data.

Aim 1

Aim 1 was to determine the content validity of the COSMOS using a survey method with a panel of expert clinicians/researchers in oncology, gerontology, and geriatric oncology and symptom management.

The content validity index (CVI) is defined as the proportion of experts who rate an item as 3 or 4 on the relevancy rating scale previously defined (Lynn, 1986; Waltz, Strickland, & Lenz, 1991). For example, if 5 out of 6 experts rate an item as 3 or 4, the CVI for that item is .83, which is the minimal level required to establish content validity at the .05 significance level (Lynn, 1986). However, Polit, Beck, and Owen (2007) suggested that a CVI for an individual item within a scale of greater than .78 can be considered as excellent agreement, regardless of the number of expert raters. The CVI for the entire subscale is the proportion of content experts who judge the overall instrument

as content valid (Lynn, 1986; Waltz et al., 1991). The minimal criteria for retaining each item was a CVI of ≥.83 (an agreement of 5 out of 6 expert panelists), with $p<.05$. A limitation of using the CVI alone is that it simply reflects the proportion of agreement without accounting for panel experts' agreement by chance. An attempt to control for this limitation is to use a conservative number of expert panelists and analyze all rating categories separately. An additional measure of agreement was also used.

The total intraclass correlation coefficient (ICC) of agreement was calculated for the comorbidity burden and symptom perception subscales and an individual ICC was calculated for each item within each subscale. The ICC has been defined as a special case of the weighted multirater kappa when rating categories are equally spaced along a single dimension (Fleiss & Cohen, 1973). The ICC (2,1) was chosen for this study, which reflects a two-way, random effects, absolute statistic. The interpretation of the multirater kappa coefficient and ICC are similar, and similar definitions and interpretations of values can be used (Fleiss & Cohen, 1973). The level of strength of agreement of ICC can be described as follows: a value of <.40 is considered poor strength of agreement, .40–.59 is fair strength, .60–.74 is good strength, and ≥.75 is excellent strength (Cicchetti, 1984; Fleiss 1971; Wynd, Schmidt, & Schaefer, 2003). The evaluation of the content validity results was based on the absolute responses of 6 expert panelists using both the CVI and ICC. The minimal criteria for retaining each item is a CVI of ≥.83 (an agreement of 5 out of 6 expert panelists), with $p<.05$ and an ICC of ≥.60. Of note, a CVI of .80 was used for two items that were answered by only 4 experts. Subscale revisions were based on the interrater agreement of the expert panel and their qualitative comments. Decision rules regarding items included the following:

- Items with CVI≥.80 and ICC≥.60 were retained for pilot testing.
- Items with CVI of .5–.79 (identified as having potential relevancy) were revised and incorporated into the tool.
- Items identified as omissions by ≥2 panelists were developed and added to the tool.
- Recommendations identified in the comments of ≥2 expert panelists were considered for incorporation into the revised tool prior to pilot testing.

Descriptive interview data such as comments on specific aspects of the overall scale, including clarity of instructions, time frames of patient experiences, critical omissions from each scale, suggestions for specific item revision, tool format, and general overall comments about the tool, were analyzed to identify key critique elements based on the categories listed above. Following the comprehensive generation of items and review by experts in the field, final decisions were made regarding item inclusion and the final format of the instrument was prepared for administration to a representative target sample.

Pilot Test of COSMOS

Sample and Setting

A convenience sample of 62 participants was recruited from outpatient care settings in southwest Arizona. Initial participant contacts were made via primary cancer care providers at a comprehensive cancer center affiliated with a university teaching hospital after appropriate eligibility screening. In addition, participants were recruited from a variety of community groups, including faith communities and cancer support groups. Participant eligibility criteria for pilot testing of COSMOS included:

- Age>65 years;
- Cancer diagnosis≥2 months;

- ≥2 comorbidities, as documented in the medical record;
- ≥1 symptoms, as documented in the medical record;
- The ability to read, write, comprehend, and speak English; and
- A Mini Mental Status Exam (MMSE) score of ≥23. The first 40 participants were screened using the MMSE. It was found that this screening criterion was very consistent, and resulted in no potential participants being ruled out. Due to the consistent screening results, this criterion was dropped so as to facilitate recruitment and study enrollment.

Participants were stratified into two groups according to treatment status. Both men and women undergoing active cancer therapy (chemotherapy, radiation therapy, biotherapy, hormonal therapy, and up to 2 weeks after cancer-related surgery) or those who were ≥1 year off of cancer-related treatment were recruited. Convenience quota sampling was used until there were at least 30 participants in each group.

Power Analysis

This phase required the careful consideration of sample size, which facilitated initial scale development. The determination of an appropriate sample size was crucial to the accurate development of the instrument. If a sample size is too small, it will lead to inaccurate internal consistency calculations, yielding an erroneous inclusion or exclusion of items and diminished applicability across populations (DeVellis, 2003).

Several discussions about sample size in pilot studies have been published. Julious (2005) suggested that a minimum of 12 participants per group should be considered for studies in the medical field. This suggestion is congruent with van Belle's (2002) assertion that at least 12 observations should be used in constructing a confidence interval. More recently, Johanson and Brooks (2010) recommended that 30 representative participants recruited from the population of interest is reasonable for a pilot study

focused on preliminary scale development.

Hertzog (2008) published an extensive discussion of the determination of sample size for pilot studies based on the construction of confidence intervals (CIs) and attrition rates. It is suggested that a sufficient sample size of 10 participants for simple instrumentation issues such as clarity of instructions, item wording, and instrument administration issues is appropriate. Hertzog suggested that a CI of at least 90% be observed when measuring internal consistency and test-retest reliability. Based on Hertzog's calculations, a minimal sample size of 35–40 per group for test-retest reliability (r = .70–.80) and 25–40 per group for internal consistency (Cronbach's alpha$\geq$.70) is suggested. The minimal recommendation for sample sizes related to instrumentation is 25 participants per group, although 35–40 participants per group are preferred (Hertzog, 2008).

The calculation of sample size using optimal statistical power is a widely accepted method of determining a statistically supported sample size for a pilot. *A priori* statistical power calculation based on the preliminary exploration of the performance of a newly developed measure for comorbidity burden and symptom perception was performed. Sample size was based upon an anticipated effect size, desired power of .8, and significance of $p\leq.05$ (two-tailed).

Effect size was calculated based on studies that reported similar variables based on similar study populations. Bender et al. (2008) reported on a study that examined symptom clusters in adults with chronic health problems, including both cancer survivors and participants with no cancer history (n = 154 and n = 846, respectively), who had an average age of 66.3 years (SD = 13.6). The researchers reported a mean of 6.8 (SD = 2.9)

comorbidities in cancer survivors and a mean of 5.1 (*SD* = 2.9) comorbidities in participants with no cancer history. A moderate effect size of .59 was calculated, indicating that it was anticipated that a moderate difference might be detected between the number of comorbidities in the cancer and noncancer survivor populations. It was likely that this difference would include the measure of comorbidity burden that accounts for presence of the comorbidity and its effect on the individual's everyday life.

The effect size for symptom burden was calculated using information from Heidrich, Egan, Hengudomsub, and Randolph (2006), who conducted a comparative study of women aged 65 and older, including 18 breast cancer survivors and 24 women without a breast cancer history. They found no significant group differences with regard to symptom presence, bother, and chronic health problems. Based on this study population, the calculated effect size for symptom presence (.079), symptom bother (.125), and chronic health problems (.31) can be considered small. The populations described in the study conducted by Bender et al. (2008) were also examined for symptom presence. Bender and colleagues found no difference between the symptom presence of cancer survivors (*M* = 7.8, *SD* = 4.3) and those with no cancer history (*M* = 7.8, *SD* = 4.4). Both studies supported the conclusion that there is a very small difference between the symptoms reported by cancer populations and noncancer populations. It is important to note that the treatment statuses of these two study populations were not clearly described. The examination of the sensitivity of an instrument to detect a moderate difference between cancer survivors on active treatment and those off treatment for 1 of more years may yield valuable information about cancer-related symptom management and long-term follow up. Data used in the calculation of effect size are

presented in Table 3.3.

The sample size for comorbidity presence was calculated for a moderate anticipated effect size (Cohen's *d* = .5) with power of .8 and resulted in 128 participants (64 participants/group) (Lenth, 2009; Soper, 2012). In addition, the sample size for symptom burden was calculated for a small anticipated effect size (Cohen's *d* = .3) with power of .8 and resulted in 788 participants (394 participants/group) (Lenth, 2009; Soper, 2012). The results of the sample size calculation for anticipated small and moderate effect sizes extend beyond the minimal recommendation of 25–40 participants per group for instrumentation pilot studies (Hertzog, 2008; Johanson & Brooks, 2010), and were not reasonable or feasible for this study.

Table 3.3

Data Used in the Calculation of Effect Size

Study	Number of Comorbidities Reported	Number of Symptoms Reported	Symptom Burden Score (Presence & Bother)
Bender et al., 2008			
With cancer (all types): *n* = 154 No cancer history: *n* = 846	With cancer: *M* = 6.8 (*SD* = 2.9) No cancer history: *M* = 5.1 (*SD* = 2.9) Estimated effect size = .59	With cancer: *M* = 7.8 (*SD* = 4.2) No cancer history: *M* = 7.8 (*SD* = 4.4) Estimated effect size = 0	With cancer: Not applicable No cancer history: Not applicable
Heidrich, Egan, Hengudomsub, & Randolph, 2006			
With breast cancer: *n* = 18 No breast cancer history: *n* = 24	With cancer: *M* = 5.44 (*SD* = 4) No cancer history: *M* = 4.5 (*SD* = 2) Estimated effect size = .31	With cancer: *M* = 12.17 (*SD* = 5.88) No cancer history: *M* = 11.75 (*SD* = 4.79) Estimated effect size = .079	With cancer: *M* = .84 (*SD* = .54) No cancer history: *M* = .75 (*SD* = .4) Estimated effect size = .125

Based on current literature, power analysis, and considerations of feasibility of recruitment of a vulnerable population, a recruitment goal of 30 participants in each treatment group, with an anticipated yield of 25 complete data sets per group, was reasonable (Hertzog, 2008; Johanson & Brooks, 2010).

Instrumentation

The MMSE was initially used to screen potential participants for their cognitive capacity to participate in the study. The MMSE is designed to assess global cognitive status and requires 5–10 minutes to administer, although it is not a timed test (Folstein, Folstein, & McHugh, 1975). The MMSE has been used in a wide variety of populations and is a valid and reliable measure of global cognitive status. This measure consists of two parts; the first requires verbal responses only and assesses orientation, memory, and attention, while the second assesses the ability to name objects, follow verbal and written commands, write a sentence, and copy a pentagon. The maximum score is 30, and lower scores indicate lower cognitive functioning. In a study by Crum, Anthony, Bassett, and Fulstein (1993), 18,056 adults were assessed with the MMSE and their results were correlated with age and education. The results of this study indicate that MMSE scores decrease with age and that lower educational background is associated with lower MMSE scores. This study suggests that the usual cutoff score of 23 yields a sensitivity of 87% and a specificity of 82% for determining cognitive functioning (Crum et al., 1993).

COSMOS v2 was used to measure comorbidity burden and symptom perception (symptom presence, distress, and attribution) in older adults with cancer. The intent of this scale is to measure several physiological and psychological factors, as described in the Perception of Unpleasant Symptoms model, that influence symptom perception such

as comorbidity burden and the presence of common symptoms. COSMOS v2 is shown in Appendix D.

A general information questionnaire (GIQ) was used to collect descriptive data on each participant, including their cancer history, medical diagnoses, current medications, marital status, living arrangements, ethnicity, income, education, perceived overall health, and quality of life. These variables are considered as antecedent factors (physical, psychological, and situational) of unpleasant symptoms, as defined by the Perception of Unpleasant Symptoms model; individual factors or groupings of these factors may have a significant impact on symptom perception. The GIQ is provided in Appendix E.

A subscale of the Functional Performance Index was used as a general measure of physical and social functioning (Leidy, 1999). The functional interference subscale (FIS) is a five-item scale that measures the general interference of health in the performance of daily activities on a six-point scale, ranging from 1 = not at all to 6 = a great deal. The scale evaluates the overall effect of general health, inclusive of comorbidity and symptoms on functional performance. The general performance level in daily activities is a consequence of situational factors such as comorbidity, anxiety, and depression, and may have an indirect impact on symptom perception.

Semistructured, audiotaped interviews were conducted with 7 study participants. Interviews included questions regarding the participants' response to the tool and their perspectives on symptoms in the context of chronic illness. Interviews were conducted with select participants until response saturation was achieved. This information was analyzed for themes to inform and further refine the tool and its content. Questions for the semistructured interview are provided in Appendix F.

Overall, measures were carefully chosen to reflect the integration of COSMOS into the Perception of Unpleasant Symptoms model as a useful tool for measuring important components of the symptom experience in older adults with cancer.

Procedure

After the revisions of the original COSMOS were completed, participants were recruited from the comprehensive cancer center affiliated with a university teaching hospital and a variety of community-based cancer survivor groups. I collaborated with health care providers to identify a convenience sample of potential participants who fit the eligibility criteria. All identified potential participants were screened for eligibility and given a participant recruitment letter that included study information; the letter is shown in Appendix G.

I explained the study to eligible participants, confirmed eligibility, and invited those eligible to engage in the study. I obtained informed consent from all participants and gave verbal and written instructions to each. A total of 32 older adults with cancer who were undergoing active treatment (chemotherapy and/or radiation therapy) and 30 who were at least 1 year posttherapy were enrolled. All participants were assessed for the ability to complete the instruments on their own; assistance was provided to those who were unable to write and/or unable to see due to physical limitations. All questionnaires were printed in 12-point font to increase readability. In addition, significant researcher–participant interactions and observations about the administration of the tool in the older adult population were noted.

Fifteen of those in the off-therapy group were invited to participate a second time within 2 to 4 weeks following initial enrollment and survey completion. Surveys and self-

addressed, stamped envelopes were mailed out to the participants. Follow-up phone call and email reminders were utilized. The participant letter for the test-retest survey packet is in Appendix H.

A convenience sample of participants was invited to participate in a semistructured interview after completing the questionnaire. Each interview was conducted via telephone and was audio recorded by me. Each participant interviewed had an opportunity to review the questionnaire prior to and during the interview. Interviews were transcribed by a research assistant and carefully checked against the tapes by me. I corrected transcripts and added specific nuances of the discussions, such as pauses, sighs, and other recorded voice sounds.

Data Analysis

Descriptive statistics were used to analyze the sample characteristics, including age, gender, ethnicity, cancer history, medical diagnoses, current medications, current cancer treatment, marital/partner status, socioeconomic status, educational level, work status, social support, living arrangements, perceived overall health, and life satisfaction.

Aim 2.0

Aim 2.0 was to determine the content validity of the COSMOS by utilizing a mixed-method approach with a group of older adults with cancer. Pretest data gathered by using COSMOS were compared to the themes identified through qualitative analysis of individual participants' discussions of the tool. Data were analyzed for congruency and clarity between quantitative and qualitative data, and were utilized as the basis for further tool revision.

Descriptive statistics were used to analyze initial COSMOS data, including frequencies and proportions of comorbidities and symptoms. Measures of central tendency were used to describe continuous scored variables such as comorbidity burden and symptom perception. Each group of symptom attributes was analyzed using frequencies and proportions as related to each specific symptom.

Each semistructured interview conducted after completion of COSMOS was audiotaped by me and transcribed by a research assistant. Data were cleaned by me prior to analysis through listening to each interview and matching it to the transcript for accuracy of discussion and additions, including voice inflection, pauses, and other parts of the discussion that may not have been transcribed. In addition, anecdotal notes taken by me were added to the qualitative data. I reviewed all transcripts and developed an initial coding schema for "chunks" of data to identify general recurrent themes. Chunks of data were organized initially using the main topics for the interview questions (specific queries about the comorbidity and symptom subscales and the overall perception of symptoms within the context of comorbidities).

Recurrent patterns of data about various aspects of the tool were incorporated into the subsequent revision of the tool. Themes identified in the qualitative data about symptom perception were used to support the symptom-attribute data for the tool.

Aim 3.0

Aim 3.0 was to determine the initial test-retest reliability of the COSMOS. The COSMOS was initially delivered to the group of older adults who finished active cancer treatment, then again 2 to 4 weeks from the initial administration date. A modified GIQ was also used to determine any changes in this group, which might affect the stability of

the measure. Data were analyzed using the ICC to determine the repeatability and stability of the survey results.

Aim 4.0

Aim 4.0 was to determine the feasibility of a self-administered measurement tool of comorbidities and symptoms in a population of older adults with cancer, including tool completion time, response patterns, tool comprehension, missing items, and patterns in missing data. Descriptive statistics were used to determine tool completion time, response patterns, and patterns of missing data. Frequencies and proportions were used for nominal data, and measures of central tendency for continuous data. Qualitative data were analyzed for themes associated with comprehension of all aspects of the instrument and for ease of administration and completion. Both quantitative and qualitative data were used to complete a full analysis of tool administration to the target population.

Aim 5.0

Aim 5.0 was to explore the sensitivity of the COSMOS between groups of older adults on active cancer treatment and those off treatment. Hypotheses tested included the following:

1. The average number of comorbidities in participant groups with cancer on active treatment and cancer survivors is the same.
2. Cancer survivors off treatment will attribute their symptoms to aging more than those who are on active treatment.
3. Participants on active treatment will report more symptoms than participants off treatment, with increased symptom perception and attribution to cancer-related treatment.

Secondary Aim

The secondary aim was to explore the relationship of comorbidities and symptoms and general functioning. Hypotheses tested included the following:

1. Increased comorbidity burden is associated with increased symptom perception.
2. Increased comorbidity burden and symptom perception are associated with increased interference in the performance of daily activities.

Descriptive statistics were used to analyze demographic data, including proportions and frequencies for nominal data and measures of central tendency for continuous data. Select demographic data such as age, gender, ethnicity, cancer history, medical diagnoses, current medications, current cancer treatment, marital status, socioeconomic status, social support, living arrangements, and perceived overall life satisfaction were correlated with comorbidity burden, symptom burden, symptom distress, symptom attribution, and general functioning. Differences between groups with regard to demographic data, comorbidities, symptoms, comorbidity burden, symptom perception, and general functioning were explored using an independent samples *t* test for continuous variables and Chi Square test for dichotomous variables. Variance between the two groups of participants assisted in determining initial measurement sensitivity. In addition, functional interference scores were correlated with comorbidity burden, symptom perception, and symptom attribution.

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CHAPTER 4

SYMPTOM EXPERIENCE AND CHRONIC ILLNESS IN OLDER ADULT CANCER SURVIVORS: AN EVIDENCE-BASED REVIEW

Abstract

The purpose of this study was to review the current evidence that explores the relationship between chronic illness and the symptom experience in older cancer survivors. Data sources included Medline, CINAHL, PsychInfo, Embase, Academic Search Complete, and Dissertation Abstracts. Current evidence suggests that there is a relationship between the number of symptoms, the presence of symptoms, symptom bother, and the presence of comorbidities in older adults with cancer; however, evidence on the nature of these relationships is unclear and may be linked to other factors, such as the functional status of cancer survivors. Adults aged 65 and older represent more than 60% of the cancer survivor population. It is important that oncology nurses understand the complex nature of symptoms in older adults that can be attributed to a multitude of causes. This knowledge may help nurses plan and deliver comprehensive symptom management to older adults with cancer and chronic illnesses.

Introduction

Older adults are one of the most vulnerable and rapidly growing populations with cancer. By 2030, approximately 20% of the population will be 65 years or older (Federal Interagency Forum on Aging-Related Statistics, 2012). About 60% of all cancer survivors are aged 60 years and older, with nearly half (45%) of all older cancer survivors being 70 years and older (American Cancer Society, 2014). In addition, cancer often occurs along with normal and pathological changes of aging, including chronic conditions (Miller et al., 2016). The most prevalent chronic diseases and conditions in geriatric oncology patients include diabetes, venous thrombosis, osteoporosis, chronic obstructive pulmonary disease, dyslipidemia, hypertension, thyroid dysfunction, obesity, and dementia (Deckx et al., 2012). These conditions are similar to the chronic health conditions in adults 65 years and older as described by the Federal Interagency Forum on Age-Related Statistics (2012), including hypertension, arthritis, heart disease, cancer, diabetes, chronic respiratory disease, and stroke. Comorbidity is associated with many adverse health outcomes, including the development of additional health problems, functional impairment/decreased mobility, increased hospitalizations, and the development of psychological symptoms such as anxiety and depression (Crabtree, Gray, Hildreth, O'Connell, & Brown, 2000; Gijsen et al., 2001; Guralnik, 1996).

In addition, many chronic conditions have symptoms that overlap with cancer-related symptoms. Acute and chronic symptoms can have a profound impact on an individual's survivorship trajectory and quality of life. Symptoms associated with cancer have been studied for more than three decades, and there are many tools available to measure cancer-related symptoms. Several of the most commonly used measurement

tools available for assessing cancer-related symptoms include the Symptom Distress Scale (Degner & Sloan, 1995; McCorkle & Young, 1978), Edmonton Symptom Assessment Scale (Bruera, Kuehn, Miller, Selmser, & Macmillan 1991), Memorial Symptom Assessment Scale (Portenoy et al., 1994), Rotterdam Symptom Checklist (de Haes, van Knippenberg, & Neijt, 1990), and M. D. Anderson Symptom Inventory (Cleeland et al., 2000). Clinically, general symptom assessment is somewhat standardized, but cancer symptom assessment often involves symptom clusters and other variables, which increases the complexity of comprehensive symptom assessment. There are many methods currently used to assess symptoms and symptom clusters (Lacasse & Beck, 2007).

The "normal" symptom experience for the older adult population is vaguely understood and may be correlated with the presence of chronic conditions. It has been suggested that the traditional retirement age may be a developmental marker for changes in perception of discomfort from abnormal to a normal expectation that comes with age (Williamson & Schulz, 1995). Thus, in older adults, cancer-related symptoms may be perceived as a normal part of aging or as being caused by other health problems (Repetto et al., 1998). This perception of "normal symptoms" may begin to explain the difference in symptom perception between younger adults and geriatric populations.

Some older adults may learn to cope with chronic symptoms (such as pain and fatigue) as a normal part of the aging process, and may experience less symptom distress due to their frame of reference. In addition, they may have different expectations regarding changes in functional ability when compared to younger adults. The aging frame of reference for symptom distress and an individual's meaning of aging may

normalize symptoms as part of the aging process. Symptoms are viewed in the context of the uniqueness of the individual, their life experiences, and perceptions of individual quality of life.

Reiner and Lacasse (2006) reviewed symptom correlates in the gero-oncology population based on an analysis of 27 articles focused on the relationships of specific cancer-related symptoms, symptom management, and physical functioning in older adult cancer survivors. The review explicated the interrelationship between high-incident symptoms in the population of older adult cancer survivors, such as pain, fatigue, sleep disturbance, depression, and functional loss. The integrated data from this review suggest that increased symptom severity has a negative impact on mental and physical functioning that is intensified by the presence of multiple comorbidities.

Older adults with cancer may have altered symptom perception due to their experience with co-occurring comorbidities. Altered symptom perception may affect "normal signals" to seek treatment if symptoms are perceived to be part of the aging process or due to comorbidities. Although there have been many publications in the gero-oncology literature on the topic of comorbidity and cancer, little is known about the interrelationship between comorbidity and symptoms in older cancer survivors. The purpose of this chapter is to review the current evidence exploring the relationship between chronic illness and the symptom experience in older cancer survivors.

Methods

The following clinical questions were used to guide this evidence-based review of relevant literature addressing chronic illness and symptoms in cancer survivors:

1. What evidence is currently available to describe the influence of chronic

illness on the symptom experience of older cancer survivors?

2. How are symptoms and comorbidity measured in symptom-related research on older adults with cancer?
3. What are the current conceptual frameworks being used for understanding the relationship between comorbidities and symptoms?

Definitions

Chronic illnesses may co-occur, such as arthritis and hypertension, or occur sequentially, such as diabetes and renal failure. Each illness may have acute exacerbations influenced by progression of another condition, treatment regimes, or changes in psychological or social circumstances. Comorbidity is defined in this review as the presence of one or more chronic conditions in addition to cancer.

Symptoms are defined as an unpleasant sensation, which may have a rapid or gradual onset and last for moments or months or years. Symptoms are "subjective experiences reflecting changes in a person's biopsychosocial function, sensation, or cognition" (University of California, San Francisco School of Nursing Symptom Management Faculty Group, 1994, p. 273). Symptom burden is defined as a subjective but quantifiable symptom presence, its frequency, and its severity, that places a physiological burden on patients and results in negative physical and emotional human responses (Gapstur, 2007).

Search Strategy

A literature search was conducted using the following inclusion criteria: publications in peer-reviewed journals from July 1993 to March 2016. Literature included in the review had the following characteristics: study population of cancer survivors either on or beyond treatment with a mean age of 60 years or older, focus on cancer-

related symptoms, greater than two symptoms, and comorbidity measured and analyzed in the study. The databases used in this search included MEDLINE, CINAHL, PsychInfo, EMBASE, Academic Search Complete, and Dissertation Abstracts. Exclusion criteria included articles written in a language other than English, review articles, case studies, articles with a primary focus on cancer diagnoses and specific treatments, symptoms leading to cancer diagnosis, supportive care and symptom interventions, and symptoms related to end-of-life care. Search terms included *aged*, *elderly*, *geriatric cancer survivor*, *gero-oncology*, *cancer symptoms*, *symptom distress*, *symptom clusters*, *comorbidity*, and *chronic illness*. The search string that yielded the most relevant studies was *aged/elderly*, *cancer survivor*, *symptoms*, and *comorbidity*. The words *comorbidity* and *chronic illness* were interchanged within the search and the term *comorbidity* had a higher yield of relevant articles. The initial search yielded 163 unique publications. Titles and abstracts were screened by the author for relevance and inclusion criteria. A focused search expansion of oncology nursing and interprofessional journals published from 2010 to 2016 yielded eight additional relevant publications. A critical review of the identified publications yielded 20 relevant publications that met the inclusion criteria.

Results and Discussion

Based on the inclusion criteria, 20 studies were selected to include in this review. A flow chart summarizing the results of the search is included in Figure 4.1. One group of studies ($N = 8$) included participants from one large database developed by a team of researchers at the University of Michigan (Gift, Jablonski, Stommel, & Given, 2004; Given, Given, Azzouz, Kozachik, & Stommel, 2001; Given, Given, Azzouz, & Stommel, 2001; Hodgson & Given, 2004; Kozachik & Badeen-Roche, 2008; Kurtz, Kurtz,

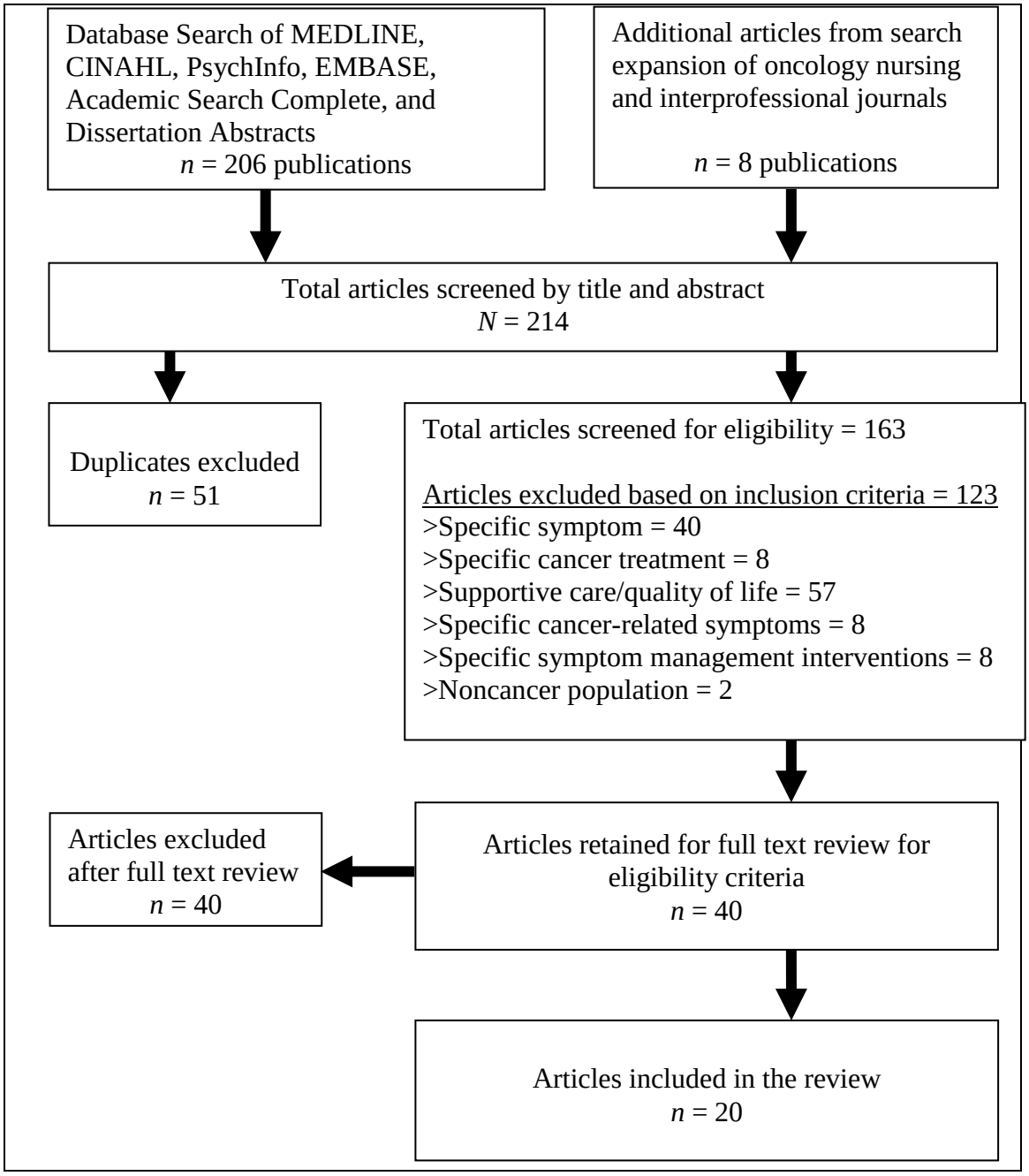

Figure 4.1 Flow chart depicting results of the literature search strategy.

Stommel, Given, & Given, 1999, 2000, 2001). The original database used by this group of studies was developed from 1993 to 1997, was focused on community-based home care in an older adult cancer survivor population, and included participants from 28 hospitals and cancer centers in Michigan and one cancer center in Indiana. There were more than 800 participants in this study group, who were 65 years and older and were newly diagnosed with breast, colon, prostate, or lung cancer; almost half (48%) had three or more comorbidities. In addition, each of the eight studies measured symptoms, comorbidities, and physical functioning. Two out of the eight studies reported on the lung cancer subpopulation (Gift et al., 2004; Kurtz et al., 2000); four out of eight explored symptom clusters within the study population, including pain, fatigue, and insomnia (Gift et al., 2004; Given et al., 2001; Given, Given, Azzouz, & Stommel, 2001; Kozachik & Bandeen-Roche, 2008). This group of studies was clustered for this chapter in order to minimize sampling bias, and is referred to as the Given-Kurtz studies. These studies are described in Table 4.1.

Twelve other studies met selection criteria (Beck, Towsley, Caserta, Lindau, & Dudley, 2009; Bellury, Pett, Ellington, Beck, Clark, & Stein, 2012; Bender et al., 2008; Cohen, Lan, Archer, & Kornblith, 2012; Deimling, Sterns, Bowman, & Kahana, 2005; Grov, Fossa, & Dahl, 2011; Heidrich, Egan, Hengudomsub, & Randolph, 2006; Loerzel, 2015; Mao et al., 2007; Royer, Phelan, & Heidrich, 2009; Spoelstra et al., 2015; Van Cleave, Egleston, Ercolano, & McCorkle, 2013). The details of these studies are presented in Table 4.2. Four out of the 12 studies were focused on female breast cancer in the older adult population (Bellury et al., 2012; Cohen et al., 2012; Heidrich et al., 2006; Royer et al., 2009). Two studies explored comorbidities and ongoing symptoms in long-

Table 4.1

Table of Evidence: Symptom Experience and Comorbidity in Older Adults with Cancer—Given-Kurtz Studies

Authors, Type of Study, and Purpose	Variables of Interest	Sample Description	Focused Findings
Gift, Jablonski, Stommel, & Given, 2004 Type of study: Secondary analysis, descriptive, correlational Purpose: Explore co-occurrence of symptoms, variance of symptom in relation to antecedents, and the effect of co-occurring symptoms on patient functional performance	Cancer therapy Comorbidity Gender Physical functioning Stage of disease Symptom occurrence Symptom severity	*N* = 220 Age: *M* = 72 years; *SD* = 7.5 Gender: 61% female Cancer diagnosis: Newly diagnosed lung cancer with 62% in Stage 3 or 4 Treatment status: 69% on active treatment Number of comorbidities: *M* = 3.5 (range: 1–9)	Number of comorbidities was one of the significant predictors for an identified symptom cluster (fatigue, nausea, weakness, appetite loss, altered taste, and vomiting) for lung cancer patients Patients with more comorbidities tended to report more symptoms ($F = 2.84$, $df = 9$, $p<.004$) Patients receiving chemotherapy reported more symptoms than those not on chemotherapy.
Given, Given, Azzouz, Kozachik & Stommel, 2001 Type of study: Exploratory, correlational, longitudinal Purpose: Examine co-occurrence and patterns of change in pain, fatigue, and other symptoms in newly diagnosed older adult patients	Age Cancer site and stage Comorbidity Gender Specific symptoms: Pain, fatigue	*N* = 841 Age: ≥65yrs Gender: 45% female Cancer diagnosis: Newly diagnosed breast, colon, lung, and prostate cancer Treatment status: >40 or <40 days after surgery or radiation therapy and >40 or <40 days into chemotherapy or no therapy Number of comorbidities: 74% of study population with 2 or more	Patients with ≥3 comorbid conditions tended to report both increased pain and increased fatigue and had significantly more symptoms overall. Patients within 40 days of surgery and radiation therapy were more likely to report pain and fatigue. Patients within 40 days of chemotherapy were more likely to report fatigue.
Given, Given, Azzouz, & Stommel, 2001 Type of study: Exploratory, correlational, longitudinal	Age Cancer site and stage Comorbidity Physical function	*N* = 826 Age: ≥65 years Gender: 41%–50% female (varied by diagnosis)	The symptom cluster of pain, fatigue, and insomnia was a significant predictor of functional decline. Patients with two or more comorbidities had

Table 4.1 (Continued)

Authors, Type of Study, and Purpose	Variables of Interest	Sample Description	Focused Findings
Given, Given, Azzouz, & Stommel, 2001 (continued) Purpose: Determine the effect of initial cancer treatments on patients' levels of physical functioning prior to and at 6 weeks following diagnosis	Symptom cluster: Pain, fatigue, and insomnia	Cancer diagnosis: Newly diagnosed breast, colon, lung, and prostate cancer Treatment status: Varied with each disease; time frame of treatment to data collection undisclosed Number of comorbidities: 25% = 0, 30% = 1, 45% = 2 or more	greater odds of decreased physical functioning. Patients on multimodal treatment regimens combined with the patient-reported symptom cluster of pain, fatigue, and insomnia had increased likelihood of functional status deterioration.
Hodgson & Given, 2004 Type of study: Secondary analysis, exploratory, descriptive, correlational Purpose: Examine the factors associated with recovery of functional ability of older adults following cancer-related surgery	Age Comorbidity Physical function Symptom severity Well-being: Mental, social	*N* = 172 Age: ≥65 years Gender: 43% female Cancer diagnosis: Newly diagnosed breast, colon, lung, and prostate cancer Treatment status: Postop for 4 to 16 weeks Number of comorbidities: *M* = 2.59; *SD* = 1.72 (range: 0–13)	A higher number of comorbidities were associated with decreased functional recovery after surgery. A higher number of reported symptoms and increased symptom severity were associated with a decreased likelihood of functional recovery after surgery.
Kozachik & Bandeen-Roche, 2008 Type of study: Secondary analysis, exploratory, descriptive, correlational Purpose: Explore patient, disease, and treatment characteristics that predict patterns of the symptom cluster of pain, fatigue, and insomnia during the first year of a cancer diagnosis	Age Cancer site and stage Comorbidity Gender Stage of disease Symptom cluster: Pain, fatigue, insomnia Treatment type Well-being: Mental	*N* = 867 Age: ≥65 years (*M* = 72.6 years) Gender: 46% female Cancer diagnosis: Newly diagnosed breast, colon, lung, and prostate cancer Treatment status: Initial diagnosis, treatment, and posttreatment Number of comorbidities: *M* = 2.7 (27% with ≥4) Number of symptoms: *M* = 7.9	The prevalence of pain, fatigue, and insomnia (PFI) changed throughout the cancer diagnosis and treatment period. The relative risk of reported PFI peaked at the midpoint of cancer therapy and diminished by 1 year after diagnosis. Comorbidity was a significant predictor of PFI at initial diagnosis and 1 year after diagnosis.

Table 4.1 (Continued)

Authors, Type of Study, and Purpose	Variables of Interest	Sample Description	Focused Findings
Kurtz, Kurtz, Stommel, Given, & Given (1999) Type of study: Exploratory, descriptive, correlational Purpose: Determine the influence of comorbidity, type of cancer, and age on symptom reporting and mental health in older adult women	Age Cancer site and stage Comorbidity Physical function Symptoms	*N* = 299 Age: ≥65 years (*M* = 73 years) Gender: 100% female Cancer diagnosis: Breast, colon, and lung cancer Treatment status: 6 months after surgery and on adjuvant therapy Number of comorbidities: *M* = 2.68 (Range: 0–13)	Age, type of cancer, and number of comorbidities are predictors of symptom severity. There is a minimal relationship between number of comorbidities and symptom severity (r = .15, p<.009), physical functioning (r = .174, p< .003), and age (r = -.269, p<.001). Increased symptom severity, advanced age, and increased comorbid conditions correspond to increased loss of physical functioning.
Kurtz, Kurtz, Stommel, Given, & Given, 2000 Type of study: Cross-sectional, exploratory, descriptive, correlational Purpose: Examine the determinants of functional loss in older adults with lung cancer	Age Cancer site & stage Comorbidity Physical function Symptom severity	*N* = 129 Age: Age: ≥65 years (*M* = 71.7 years) Gender: 42% female Cancer diagnosis: Lung cancer (late stage) Treatment status: 45.8% with surgery, radiation therapy, or chemotherapy only; 54.2% on multimodality therapy Number of comorbidities: *M* = 3.1 (*SD* = 1.81)	Patients who reported higher symptom severities tended to be older and reported more comorbidities. Symptom severity, prediagnosis physical function, and age were significant in predicting loss of physical function during treatment.
Kurtz, Kurtz, Stommel, Given, & Given, 2001 Type of study: Exploratory, descriptive, correlational Purpose: Explore the determinants of physical functioning deficit and their influence on depressive symptoms in older adults with	Age Cancer site and stage Comorbidity Gender Physical function Symptom severity Treatment type	*N* = 420 Age: 65–98 years Gender: 57.6% female Cancer diagnosis: Breast, colon, lung, and prostate cancer (75% with Stage I or II disease) Treatment status: 47.9% with surgery only; 52.1% with surgery and adjuvant radiation or chemotherapy	Symptom severity was moderately related to comorbidity (r = .329, p = .05). Symptoms of depression were moderately related to symptom severity (r = .51, p = .05). Comorbidity was inversely related to physical functioning at prediagnosis (r = .32, p = .05). Increased comorbidity was also associated

with decreased physical function both

Table 4.1 (Continued)

Authors, Type of Study, and Purpose	Variables of Interest	Sample Description	Focused Findings
Kurtz, Kurtz, Stommel, Given, & Given, 2001 (continued) cancer		Number of comorbidities: *M* = 2.7 (*SD* = 1.60)	prediagnosis and posttreatment.

Table 4.2

Table of Evidence: Symptom Experience and Comorbidity in Older Adults With Cancer

Authors, Type of Study, and Purpose	Variables of Interest	Sample Description	Focused Findings
Beck, Towsley, Caserta, Lindau, & Dudley, 2009 Type of study: Descriptive, comparative, repeated measures Purpose: Explore characteristics of and relationships between the symptom experience, health-related quality of life, and functional performance of older adult cancer patients at 1 and 3 months posttreatment	Comorbidity Physical functioning Quality of life Specific symptoms: Pain, fatigue, sleep quality, depression	*N* = 52 Age: *M* = 71.54years (*SD* = 4.92) Gender: 44.2% female Cancer diagnosis: Prostate, breast, other cancer Treatment history: Radiation therapy = 73.1% Chemotherapy = 19.2% Both radiation and chemotherapy = 7.7% Number of symptoms: *M* = 4.58 (1 month after treatment completion); (*M* = 3.9 (3 months after treatment) Number of comorbidities: *M* = 3.5 (range: 1–9) (88% of participants reported comorbidities, with 25% reporting ≥3 comorbidities) (≥3 comorbidities = ~25%	Cancer survivors reported 1–13 symptoms. The most commonly reported symptoms included urinary frequency, pain, cough, and shortness of breath. The most commonly reported symptoms had a moderate symptom severity (range: 2.6–3.16). The most frequently reported comorbidities were arthritis (38.5%), diabetes (25%), hypertension (23.1%), and heart disease (21.2%). The number of comorbidities was significantly correlated with three symptoms: fatigue (*r* = .31), depression (*r* = .43), and global sleep quality (*r* = .38).
Bellury, Pett, Ellington, Beck, Clark, & Stein, 2012 Type of study: Secondary analysis, exploratory, descriptive Purpose: Evaluate a conceptual model of gero-oncology survivorship, including dimensions of aging, cancer,	Comorbidity Physical function Social support Symptoms	*N* = 759 Age: *M* = 77.6 years (*SD* = 5.3) Gender: 100% female Cancer diagnosis: Breast cancer Treatment history: *M* = 2.7 modalities (*SD* = 1.5) * Surgery = 90.9% * Hormone therapy = 8.8% * Radiation therapy = 5.9%	Symptom bother was strongly correlated with comorbidity (*r*= .45) and physical activity (*r*= -.49). Symptom bother and comorbidity were stable across survivorship cohorts. Increased comorbidity was associated with more symptoms and decreased physical functioning.

Table 4.2 (Continued)

Authors, Type of Study, and Purpose	Variables of Interest	Sample Description	Focused Findings
Bellury, Pett, Ellington, Beck, Clark, & Stein, 2012 (continued) and symptoms, on functioning		* Chemotherapy = 37.7% Length of survivorship: 29.4% at 2 years, 33.6% at 5 years, 37% at 10 years Symptom assessment: *M* = 44.8 (*SD* = 9.7; range = 30–112.5) Comorbidities: *M* = 2.3 (*SD* = 1.8)	
Bender et al., 2008 Type of study: Secondary analysis (two separate studies used), exploratory, descriptive Purpose: Identify and compare symptom clusters in cancer survivors with chronic illness and adults with noncancer chronic illness	Comorbidity Quality of life Symptoms Symptom clusters	*N* = 154 with cancer history and 485 without cancer history Age: *M* = 66.5 (*SD* = 13.6 years) Gender: Women>men Cancer diagnosis: All types; primarily breast, prostate, melanoma, colon, and gynecological cancers Treatment status of cancer survivors: 30% on active treatment Number of comorbidities: Participants with cancer: *M* = 6.8 (*SD* = 2.9) Participants without cancer: *M* = 5.1 (*SD* = 2.9) Number of symptoms: Subjects with cancer: *M* = 7.8 (*SD* = 4.2) Subjects without cancer: *M* = 7.8 (*SD* = 4.4)	A similar symptom cluster (pain, fatigue, and sleep disturbance) was found in those with cancer and comorbidities and those with cancer only. Most study participants (97%) reported that their cancer was controlled, which suggests that symptoms reported may have been due to chronic conditions. Participants with a cancer history reported significantly more comorbidities than those with no cancer history (*p*< .001). The most prevalent comorbidities or chronic conditions reported included cardiovascular disease (44%), hypertension (41%), osteoarthritis (44%), and urinary incontinence (49%). Symptom clusters tended to be clusters associated with the participants' primary chronic illness. Symptoms that had a significant effect on quality of life were mostly related to the primary chronic illness.
Cohen, Lan, Archer, & Kornblith, 2012 Type of study: Descriptive, correlational	Age Comorbidity Physical function Role function	*N* = 153 Age: <65 years = 79; >65 years = 74 Gender: 100% female Cancer diagnosis: Breast cancer	Older participants had significantly more multimorbidities than those <65 years. The most prevalent comorbidities in those >65 years included arthritis (59.5%),

Table 4/2 (Continued)

Authors, Type of Study, and Purpose	Variables of Interest	Sample Description	Focused Findings
Cohen, Lan, Archer, & Kornblith, 2012 (continued) Purpose: Assess the impact of age, comorbidities, and symptoms on the functional status of long-term cancer survivors	Symptoms	Treatment status: Off treatment (data collected from cancer survivors 17–25 years after diagnosis) Number of comorbidities: <65 years = 57% with >1 comorbidity ≥65 years = 75.7% with >1 comorbidity	hypertension (47%), heart trouble (24.3%), circulation problems (24.3%), and osteoporosis (21.6%). Only hypertension was significantly (p< .001) higher in participants >65 years. The most common reported symptoms included fatigue, pain, insomnia, and dyspnea. There was no difference in reported symptoms between age groups. Symptoms had significantly stronger association (F= 53.6, p<.001) than comorbidities (F = 27.5, p< .001) with decreased physical function.
Deimling, Sterns, Bowman, & Kahana, 2005 Type of study: Descriptive, correlational Purpose: Explore comorbidities, symptoms, and select characteristics of long-term older cancer survivors and their association with health and functioning	Cancer treatment Comorbidity Gender Symptoms Treatment type	N = 321 Age: M = 72.3 years (SD = 7.5) (85% participants≥65 years) Gender: 59.2% female Cancer diagnosis: Breast (41.4%), colorectal (29.9%), and prostate cancer (28.7%) Treatment status: Long-term cancer survivors ≥5 years after treatment and diagnosis Number of comorbidities: M = 3.7 (SD = 2.4)	Slightly more than a third (37.7%) of survivors had ≥1 symptoms attributed to cancer and treatment. One third of cancer survivors reported five or more chronic health conditions such as hypertension, allergies, back problems, heart trouble, or urinary tract disorders.
Grov, Fossa, & Dahl, 2011 Type of study: Cross-sectional, correlational, comparative Purpose: Examine comorbidity, symptoms, lifestyle, and psychosocial determinants of	Activities of daily living Cancer survivor time Comorbidity Instrumental activities of daily living Physical function	N = 479 Short-term survivors (1–5 years) = 265; long-term survivors (>5 years) = 214 Age: M = 77.3 years (SD = 5.4) (all participants >70 years) Gender: 46.5% female	No significant difference was found between older cancer survivors and age and gender-matched controls regarding number of self-reported comorbidities and symptoms. However, older cancer survivors reported significantly higher use of daily medications (73%) than controls

Table 4.2 (Continued)

Authors, Type of Study, and Purpose	Variables of Interest	Sample Description	Focused Findings
Grov, Fossa, & Dahl, 2011 (continued) older cancer survivors as compared to age and gender-matched sample without cancer	Specific symptoms: Somatic, anxiety, depression Well-being: Mental	Cancer diagnosis: Gastrointestinal (23%), prostate (22%), breast (16%), and other cancers (39%) Number of comorbidities: >2 comorbidities in 43% of short-term survivors and 34% of long-term survivors	(65%) (p = .0005). Common symptoms reported by both short- and long-term survivors included muscular pain and stiffness (26%–75%, depending on anatomical site), headache (19%), gastrointestinal complaints (13%), and somatic complaints (12%). Common comorbidities reported in both short- and long-term survivors included hypertension (35%), arthritis (28%), diabetes (12%), asthma, and thyroid disease, osteoporosis, and musculoskeletal disease (8% each).
Heidrich, Egan, Hengudomsub, & Randolph, 2006 Type of study: Descriptive, correlational Purpose: To compare symptoms, symptom beliefs, and quality of life of older female breast cancer survivors with older women without breast cancer	Comorbidity Quality of life Symptom beliefs Symptom distress	*N* = 42 Age: ≥64 years (*M* = 76 years) Gender: 100% female Cancer diagnosis: Breast cancer (42.9%) compared with women without cancer (57.1%) Treatment status: 50% breast cancer participants on Tamoxifen Number of comorbidities: *M* = 5.44 (*SD* = 4.0) for breast cancer participants Symptoms reported as high frequency: Pain (76.2%), memory problems (76.2%), joint pain (59.5%), stiffness (59.5%), dry skin (52.4%), fatigue (52.4%)	Women in both groups most often attributed symptoms to aging, chronic illness, or an unknown cause. Aging was the most frequently reported cause of symptoms, followed by chronic illness. Symptom distress was significantly associated with the belief that symptoms were caused by chronic illness (*r* = .42), breast cancer (*r* = .39), and "I don't know" (*r* = .52) (*p*< .05). Symptom distress was not found to be related to the belief that symptoms were caused by aging.
Loerzel, 2015 Type of study: Exploratory, descriptive	Comorbidity Physical function Mental function	*N* = 100 Age: ≥65 years (*M* = 71.9 years) Gender: 48% female	High-incidence comorbidities reported by participants included high blood pressure (66%), heart problems (21%), thyroid/ glandular

Table 4.2 (Continued)

Authors, Type of Study, and Purpose	Variables of Interest	Sample Description	Focused Findings
Loerzel, 2015 (continued) Purpose: To explore the symptom experience of older adults receiving chemotherapy in an outpatient setting	Symptom presence Symptom severity	Cancer diagnosis: Lung (21%), breast (18%), gastrointestinal (18%), hematologic (16%), head and neck (16%), and other cancers (11%) Treatment status: On chemotherapy Number of comorbidities: 39% of participants with 1–2; 59% of participants with >3 Number of symptoms: *M* = 7.15 (range = 2–16)	disorders (19%), and diabetes (18%). Adults aged ≥71 years reported more symptoms as compared to those aged 65–70 years. Older adults experienced a significant number of moderate to severe symptoms while receiving chemotherapy. Participants with a higher number of comorbidities reported significantly more symptoms (t = -2.335, df = 98, p = .022). Mental health functioning had a positive relationship with the number of symptoms. Instrumental and physical activities of daily living were decreased in participants reporting a higher number of symptoms and comorbidities.
Mao, Armstrong, Bowman, Xie, Kadakia, & Farrar, 2007 Type of study: Descriptive, comparative Purpose: To understand the symptom burden among community-dwelling cancer survivors	Comorbidity Symptoms	*N* = 1,904 cancer survivors Age: 50.2% ≥65 years 47.8% ≤5 years since diagnosis; 52.2% 5 years since diagnosis Gender: 58.8% female Cancer diagnosis: Breast (17.1%), gynecological (14.9%), prostate (10.2%), and colorectal cancer (9.3%) Treatment status: Unknown Number of comorbidities: 21.7% had two or more Symptoms reported as high frequency: Pain (34%), insomnia (30%), psychological—anxiety and depression (26%)	Cancer survivorship and comorbidity were associated with higher symptom burden. Cancer survivors with two comorbidities had higher risk of pain (*OR* = 17.39), psychological distress (*OR* = 7.38), and insomnia (*OR* = 7.71). Cancer survivors with three or more comorbidities had a significantly higher risk of experiencing pain (*OR* = 35.56), psychological distress (*OR* = 15.12), and insomnia (*OR* = 10.25). Cancer survivors ≥65 years reported lower symptom burden than those <65 years. Cancer survivors reported a higher rate of pain, psychological distress, and insomnia than controls without a cancer history.

Table 4.2 (Continued)

Authors, Type of Study, and Purpose	Variables of Interest	Sample Description	Focused Findings
Royer, Phelan, & Heidrich, 2009 Type of study: Secondary analysis, qualitative content analysis Purpose: To describe symptom representations, symptom management strategies, and perceived barriers to symptom management based on Leventhal's Common Sense Model	Comorbidity Symptoms Symptom representations	*N* = 61 Age: *M* = 69.5 years (*SD* = 5.2; range = 65–86 years) Gender: 100% female Cancer diagnosis: Breast (*M* = 4.7 years; range = 1–35 years after diagnosis) Treatment history: Mastectomy (65%), radiation therapy (51%), lumpectomy (48%), hormone therapy (35%), chemotherapy (23%) Number of comorbidities: *M* = 4.8 (range = 1–11) Number of symptoms: *M* = 17 (range = 5–30)	The highest comorbidities reported by survivors included arthritis (67%), hypertension (54%), depression (25%), and bronchitis/emphysema (21%). The highest reported symptoms included stiffness (84%), joint pain (80%), aching (79%), fatigue (77%), and pain (75%). Most women described the cause of their symptoms as having multiple factors (97%). Additional reported causes of symptoms included chronic or comorbid conditions (67%), cancer or its treatment (34%), and aging (8%). Sixty-two percent of participants reported that their symptoms caused some physical limitation.
Spoelstra et al., 2015 Type of study: Descriptive, exploratory, longitudinal Purpose: To evaluate symptom prevalence, severity, and attribution and interference with comorbidity management in patients on oral anticancer agents	Cancer therapy Comorbidity Symptom attribution Symptom occurrence Symptom severity	*N* = 30 Age: *M* = 65.1 years (*SD* = 9.8) Female: 50% Diagnosis: Colorectal (33%), leukemia (13.3%), breast (10%), and other cancers (40%) Cancer stage: 60% with Stage IV disease Treatment status: 100% on oral anticancer agents Number of comorbidities: *M* = 2 (*SD* = 1.7) (33.3% with 3 or more comorbidities)	Patients with more comorbidities tended to report higher symptom severity. The most prevalent symptoms reported included fatigue, pain, numbness and tingling, and sleep disturbance. The most commonly reported comorbidities included hypertension and cardiac disease. All participants reporting comorbidities indicated that cancer treatment interfered with self-management of comorbid conditions. Commonly reported symptom attributions included cancer treatment as the most common, followed by cancer, cancer treatment, and comorbidity.
Van Cleave, Egleston, Ercolano, & McCorkle, 2013	Cancer site Cancer treatment	*N* = 356 Age: *M* = 71.8 years (*SD* = 5.4) (45.1 %	Patients with three or more comorbidities reported increased symptom distress as compared to those

Table 4.2 (Continued)

Authors, Type of Study, and Purpose	Variables of Interest	Sample Description	Focused Findings
Van Cleave, Egleston, Ercolano, & McCorkle, 2013 (continued) Type of study: Descriptive, correlational Purpose: To determine the influence of age on symptom distress among older adults undergoing surgical intervention for a cancer diagnosis	Comorbidity Physical function Specific symptom: Psychological distress Symptom presence Symptom severity	were 65–69 years, 33.1% were 70–74 years, 21.8% were >75 years) Gender: 50.3% female Cancer diagnosis: Genitourinary (27%), gynecologic (23%), thoracic (22.4%), and digestive cancer (22.4%); 84.7% were newly diagnosed Treatment status: Surgery alone (46.6%), surgery and chemotherapy (31.6 %), surgery and radiation (9.2%), surgery, radiation, and chemotherapy (12.6%) Number of comorbidities: 67.2% with 2 or more Number of symptoms at baseline: 63.8% with three or more	with <2 comorbidities. Symptoms decreased over the normal postoperative recovery time from baseline to 3 and 6 months ($p < .002$). The majority of participants had three or more symptoms at baseline. The type of treatment was not associated with symptom distress. Participants aged ≥75 years reported greater symptom distress over the 6-month postoperative period than those aged 65–69 years ($p = .049$). Decreased physical function was liked to increased symptom distress.

term older cancer survivors who were more than 5 years beyond their cancer diagnosis (Deimling et al., 2005; Grov et al., 2011). Three studies explored the differences between older adult cancer survivors and controls with no cancer history (Bender et al., 2008; Heidrich et al., 2006; Mao et al., 2007). Eight out of these 12 studies used specific measures of symptoms, comorbidities, or chronic illnesses and physical functioning.

Influence of Chronic Illness on Symptom Experience in Older Adults With Cancer

The symptom experience of older cancer survivors can be characterized as a blend of cancer-related symptoms and those related to chronic illness, illness conditions, and aging. The Given–Kurtz studies (1999–2008) collectively suggest that cancer survivors who reported three or more comorbidities in addition to their cancer diagnosis had more symptoms ($M = 4.7$) than those who reported zero to two comorbidities. Kozachik and Bandeen-Roche (2008) examined data from 867 participants and found that symptoms of pain, fatigue, and insomnia were affected by increased comorbidities early in the cancer-treatment trajectory; however, increased comorbidity was not a significant predictor of pain, fatigue, and insomnia after the first 2 months of the cancer experience. In another study, younger age and increased number of comorbidities were significantly related to higher symptom severity in a population 6 months after cancer surgery and on chemotherapy (Kurtz et al., 1999).

Researchers in several studies concluded that their study populations demonstrated that patients with an increased number of chronic illnesses also had increased symptoms or symptom burden (Beck et al., 2009; Bellury et al., 2012; Gift et al., 2004; Given, Given, Azzouz, Kozachik, et al., 2001; Given, Given, Azzouz, &

Stommel, 2001; Hodgson & Given, 2004; Kozachik & Badeen-Roche, 2008; Kurtz et al., 1999, 2000, 2001; Loerzel, 2015; Mao et al., 2007; Spoelstra et al., 2015; Van Cleave et al., 2013). Mao and colleagues (2007) compared cancer survivors with the general population and found that cancer survivors have a higher ongoing symptom burden than those with no cancer history. The symptoms of pain, psychological distress, and insomnia were reported as ongoing symptom concerns in the study population. Grov et al. (2011) assessed symptoms in older cancer survivors and found no significant difference in symptoms reported by short-term survivors (1–5 years from diagnosis) as compared to long-term survivors (>5 years from diagnosis). Bender and colleagues (2008) examined cancer as a chronic illness and compared symptoms and symptom clusters assessed in older adults with rheumatoid arthritis and urinary incontinence with or without a cancer history. This study found that the number of symptoms reported by individuals with cancer, as compared with other chronic conditions (rheumatoid arthritis and urinary incontinence), was similar, with a mean of 7.8 (*SD* = 4) symptoms. No unique symptom clusters were found among study participants with and without cancer. The results of this study suggest that the symptoms experienced by the participants were more related to the participants' chronic health issues as compared with a cancer history.

Measurement of Symptoms

Symptom presence, symptom severity, and symptom burden (interference and severity) were measured using a variety of scales and methods in the studies selected for this review. These measures are described in Table 4.3. The Given–Kurtz studies and two others used an interview method of symptom assessment (Deimling et al., 2005; Gift et al., 2004; Given, Given, Azzouz, Kozachik, et al., 2001; Given, Given, Azzouz, &

Table 4.3

Symptom Measures Used in Studies of Older Adult Cancer Survivors

Study Authors	Symptom Measure Description	Other Symptom Measures Used
Beck, Towsley, Caserta, Lindau, & Dudley, 2009	Side Effect Checklist Self-report, 18-item scale Symptom time frame: Previous week	Brief Pain Inventory General Fatigue Scale Pittsburgh Sleep Quality Scale Geriatric Depression Scale
Bellury et al., 2012	Modified Rotterdam Symptom Checklist Self-report, 30-item scale Symptom time frame: Previous week	None
Bender et al., 2008	Comorbidity Questionnaire, symptom assessment subscale Self-report, 32 items Symptom time frame: Current	None
Cohe, Lan, Archer, & Kornblith, 2012	European Organization for Research Treatment of Cancer Self-report, 8 symptoms Symptom time frame: Current	None
Deimling, Sterns, Bowman, & Kahana, 2005	Author-constructed index based on participant interview Interview Variable based on 22 possible symptoms Symptom time frame: Current	Symptom attribution discussed during interview
Given–Kurtz, 1999–2008	Symptom Experience Scale Interview, 33–37 items Symptom time frame: Previous 2 weeks	Center for Epidemiological Studies Depression Scale (CES-D)
Grov, Fossa, & Dahl, 2011	Checklist of Somatic Disease Self-report, six major symptoms Symptom time frame: Variable per symptom	Hospital Anxiety and Depression Scale
Heidrich, Egan, Hengudomsub, & Randolph, 2006	Symptom Bother Scale–Revised Self-report, 37-item scale Symptom time frame: Current	CES-D symptom attribution subscale State-Trait Anxiety Inventory
Loerzel, 2015	Symptom Representation Questionnaire Self-report, 22 items Symptom time frame: Previous week	None
Mao et al., 2007	National Health Interview Survey Self-report, multiple nested items Symptom time frame: Previous 12 months	None

Table 4.3 (Continued)

Study Authors	Symptom Measure Description	Other Symptom Measures Used
Royer, Phelan, & Heidrich, 2009	Symptom Bother Scale Self-report, 34 items Symptom time frame: Current	None
Spoelstra et al., 2015	Symptom Experience Inventory Self-report via interview, 15 items Symptom time frame: Previous 7 days	None
Van Cleave, Egleston, Ercolano, & McCorkle, 2013	Symptom Distress Scale Self-report, 13-item scale Symptom time frame: Previous 7 days	Mental health measures (SF-12,[a] SF-36,[b] CES-D)

[a] Medical Outcomes Study: 12-item short form survey instrument.
[b] Medical Outcomes Study: 36-item short form survey instrument.

Stommel, 2001; Hodgson & Given, 2004; Kozachik & Badeen-Roche, 2008; Kurtz et al., 1999, 2000, 2001; Spoelstra et al., 2015). The majority of the studies used the self-report survey method of symptom assessment based on a specific symptom measure. Three studies used additional measures for specific symptoms (Beck et al., 2009; Heidrich et al., 2006; Van Cleave et al., 2013). In addition, a total of seven studies plus the Given–Kurtz studies used symptom measures that included assessment of symptom presence and an element of symptom burden severity, bother scales, or impact on quality of life (Beck et al., 2009; Bellury et al., 2012; Bender et al., 2008; Gift et al., 2004; Given, Given, Azzouz, Kozachik, et al., 2001; Given et al., 2001; Heidrich et al., 2006; Hodgson & Given, 2004; Kozachik & Badeen-Roche, 2008; Kurtz et al., 1999, 2000, 2001; Loerzel, 2015; Royer et al., 2009; Spoelstra et al., 2015; Van Cleave et al., 2013). The scales used to assess symptom severity ranged from three to five points, while the scales measuring symptom bother ranged from four to five points. All reviewed studies used a specific but different measure of cancer-related symptoms. Two studies using the revised Symptom Bother Scale measured symptom distress and symptom beliefs regarding the cause of symptoms, including aging, cancer, chronic illnesses, or unknown (Heidrich et al., 2006; Royer et al., 2009). Of interest, 97% of the study population reported multiple causes for most symptoms.

The most common symptoms assessed across all reviewed studies included pain, fatigue, and sleep-related problems. Items to measure pain included the following descriptors: generalized pain, back pain, joint pain, and muscle pain. Fatigue was described by the use of terms such as *lack of energy* and *tiredness*. Sleep-related problems were described using a wide array of terms, such as insomnia, *sleep*

disturbances, *problems falling asleep*, *early wakening*, and *waking too often*. Other high-frequency symptoms, reported by >30% participants in more than one study, included urinary symptoms (increased frequency and incontinence), bowel symptoms (constipation and diarrhea), decreased appetite, respiratory symptoms (dyspnea, cough), memory problems, and dry skin. The measurement of cancer symptoms was different in each study and included several dimensions of the symptom experience.

Measurement of Comorbidity

Comorbidity in the oncology population has been measured in clinical research using a variety of valid and reliable tools, including the Charlson Index, Cumulative Illness Rating Scale–Geriatric, Kaplan-Feinstein Index, and Index of Coexisting Disease (DeGroot, Beckerman, Lankhorst, & Bouter, 2003; Extermann, 2000). Many of these measures require intensive chart review and complex calculations of severity of illness. Self-report of chronic illness is another reliable method to obtain these data (Ingram et al., 2002; Katz, Chang, Sandha, Fossel, & Bates, 1996). The most common reporting of comorbidity data in cancer symptom research is a simple count of comorbidities. These data are often used as a demographic variable to assist in explaining symptom burden or symptom clusters, or as the relationship of symptoms and physical functioning, or as a covariate to equalize groups on the overall severity of illness.

Four basic measures of comorbidity were used in the studies reviewed. Six out of 11 studies used a simple checklist of chronic illnesses (Beck et al., 2009; Bellury et al., 2012; Given et al., 2001; Grov et al., 2011; Royer et al., 2009; Van Cleave et al., 2013). The majority of these studies reported a simple count of comorbidities and analyzed their impact on study variables based on the number of comorbidities. The Given-Kurtz

studies assessed comorbidities via an interview process using a simple checklist. This method has been determined to be a valid measure of comorbidity (Vaeth, Satariano, & Ragland, 2000).

Three studies used measures or questionnaires based on the Older American Resource and Service Schedule of Illnesses (OARS) questionnaire and methodology (Duke University Center for the Study of Aging and Human Development, 1978). The OARS is commonly used to assess the general health status of community-dwelling older adults. Loerzel (2015) collected comorbidity and physical functioning data using items from the OARS Multidimensional Functional Assessment Questionnaire and mental health functioning data from the psychiatric evaluation subscale. Cohen et al. (2012) used a self-report, modified version of the OARS questionnaire, which measured presence of 22 comorbidities and their degree of interference with daily activities. Heidrich and colleagues (2006) also used a modified version of the OARS that was tailored for use with older women. Deimling et al. (2005) used the Health Conditions Index, which was adapted from the OARS, and included a sum of the number of self-reported health conditions based on a list of 27 possible conditions.

Mao and colleagues (2007) used a series of interview questions around functional limitations and the health condition that was causing the limitation. Chronic conditions were then counted and presented as an absolute number. No validity or reliability data were available for this method. Bender et al. (2008) assessed both comorbidities and symptoms using the Comorbidity Questionnaire, a self-report tool based on the Charlson Comorbidity Index (Charlson, Pompei, Ales, & MacKenzie, 1987). The comorbidity subscale of this questionnaire included 32 chronic conditions on a checklist. This

subscale assessed the presence of chronic illness and whether or not (a) a health care provider diagnosed it, (b) it was present within the previous 5 years, (c) it was currently being treated, (d) it required hospitalization, and (e) its impact on quality of life.

Conceptual Frameworks Related to Cancer Symptom Research

The third research question focused on examining the use of conceptual frameworks in the reviewed studies. Six out of 20 studies identified a specific conceptual model related to symptoms to guide the study. Beck et al. (2009) used Armstrong's Symptoms Experience model to explore symptom experience, health-related quality of life, and functional performance in urban and rural older adult cancer survivors. The Symptom Experience Model (SEM) provides a general explanation of the symptom experience (Armstrong, 2003). Within this model, the symptom experience is described as the perception of symptoms with regard to frequency, degree of distress, intensity, and the meaning of each symptom. In the SEM, symptom perception includes each symptom or group of symptoms as they are experienced by the individual within the context of the meaning of symptoms (Armstrong, 2003).

Two studies used Leventhal's Common Sense Model (CSM) of symptom attribution to explore symptoms, symptom beliefs, and their relationship to quality of life (Heidrich et al., 2006), symptom management strategies, and perceived barriers to symptom management (Royer et al., 2009). The symptom experience in older adults with cancer is highly variable and reflects many antecedents to the diagnosis and treatment of cancer, including previous life experiences with chronic illness and its treatments. An individual's interpretation of his or her symptoms can be comprehensively understood by using an information-processing model such as the CSM. This model proposes that

people have specific ideas about their illnesses and that these ideas guide coping behaviors for health and illness (Haggar & Orbell, 2003; Leventhal, Meyer, & Nerenz, 1980; Ward, 1993). This general framework integrates the physical, psychological, and social dimensions of symptom perception and subsequent choices of symptom-management actions. In addition, older adults may have a multidimensional representation of aging. A study by Prohaska, Keller, Leventhal, and Leventhal (1987) revealed that mild symptoms of short or long duration are more likely to be attributed to aging than severe, short-term symptoms. In addition, the attribution of mild symptoms with gradual onset to aging resulted in a greater acceptance of symptoms with a subsequent delay in seeking health care for the symptoms (Prohaska et al., 1987).

One of the eight Given–Kurtz studies identified the Theory of Unpleasant Symptoms (TOUS) as a basis for the study (Gift et al., 2004). The TOUS incorporates three factors that influence symptoms, including physiological (including comorbidities), psychological, and situational factors (Lenz, Pugh, Milligan, Gift, & Suppe, 1997; Lenz, Suppe, Gift, Pugh, & Milligan, 1995). In this model, symptoms are thought to (a) occur in groups or clusters, (b) interact with each other, and (c) ultimately affect an individual's symptom perception, functional status, cognitive functioning, and physical performance. The TOUS model also illustrates the effect of symptoms on overall performance, such as physical and cognitive functioning that has an impact on the symptoms and the factors that preceded symptom development, such as comorbidities.

The integration of the SEM, CSM, and TOUS begins to illuminate the complexity of symptom perception by older adults with cancer and comorbidities. This population uses current body sensations, past experiences with acute and chronic illnesses and

symptoms, and related interactions with family, friends, and health care providers to make decisions about their symptoms. In addition, health care providers can use an older cancer survivor's personal perspective regarding her or his symptoms to develop a comprehensive, patient-centered symptom-management plan. Both the SEM and TOUS may be useful as frameworks for symptom management research in the gero-oncology population (Brant, Beck, & Miaskowski, 2009).

Bellury and colleagues (2011) proposed an integrated conceptual model of elderly cancer survivorship that incorporates elements of cancer survivorship, personal factors, and gero-oncology (age-related concerns and health-related issues). This model begins to illuminate the complex relationship between comorbidity, cancer, and symptoms in older adults (Bellury et al., 2011). The model enhances the general understanding of the essential elements in gero-oncology populations and may provide a basis for comprehensive interprofessional and multidisciplinary care management of older adult cancer survivors. Bellury et al. (2012) used the conceptual model of elderly cancer survivorship to explain the influence of select variables of aging, cancer, and symptoms on physical functioning of older breast cancer survivors.

A broader nursing model, the Vulnerability/Risk/Human Response model, was used by Van Cleave et al. (2013) to select specific independent and dependent variables to determine the influence of age on symptom distress in older adults with cancer who were undergoing thoracic, abdominal, or pelvic surgery. This model is based on an ecological framework of health using a biopsychosocial perspective and describes the integration of individual factors (age, cancer-related information, chronic illness, psychological health) and environmental factors (cancer-related treatment, intervention

by an advanced-practice nurse) that affect human responses such as symptom distress and physical functioning (Shaver, 1985).

In summary, multiple conceptual models are used in cancer research. The diversity of symptom-related models enhances understanding of the complex dimensions of symptom science. The diversity of conceptual frameworks used in symptom research may serve to enhance understanding of the relationships of symptom correlates in the gero-oncology population.

Limitations

This integrated review included several research studies with participants younger than 65 years and may not be fully representative of the gero-oncology population. Across the studies included in the review, there was wide variation in the gero-oncology population regarding cancer diagnoses, treatment history, and treatment status. Eight studies included in the review analyzed subsets of the same database, which increases the risk for error in drawing conclusions about the relationship between symptoms and chronic illness in cancer survivors. These studies were grouped as one study, the Given–Kurtz studies, and analyzed along with 12 additional studies for this review. The final limitation is the complexity of searching for appropriate literature to include in the review. The search strategy yielded a moderate number of studies that met the inclusion criteria; however, several articles were added after a hand search, and studies may have been missed.

Conclusions

Although the specialty of gero-oncology has grown over the past 10 years, there is minimal consistent data available to draw specific conclusions about the relationship

between cancer, comorbidity, and symptoms in older adults. This may relate to the perception of cancer as a chronic illness and the complexity of the relationship between chronic illnesses and symptoms within the context of the expected changes of aging. A moderate relationship between chronic illness and symptoms was reported across studies and ranged from $r = .31$ (depression only) to $r = .45$ (symptom bother). In addition, physical and mental functional interference is intertwined with the perception of interference of both symptoms and chronic illness (Reiner & Lacasse, 2006).

There is a wide range of measures used in research that address symptoms, comorbidity, and cancer in older adults. The nonstandard measures used across studies create a challenge for comparing the symptom characteristics and comorbidities and their relationship across populations. While there is a list of core of symptoms assessed in the cancer population, there is a wide variety of cancer symptom assessment lists. Similarly, there is a wide range of comorbidities that are assessed in studies on cancer survivors. Several studies reported a list of common comorbidities usually found in older adults, while others reported lists that incorporated symptom-related chronic conditions, such as anxiety and depression, and geriatric syndromes, such as vision and hearing impairment, balance problems, memory problems, and urinary incontinence. In addition, there is wide variation in the time frame for reporting symptoms, ranging from "over the past week" to "during the past year." The recent development of Patient-Reported Outcomes Measurement Information System tools (www.healthmeasures.net/explore-measurement-systems/promis) may provide some standardization to measurement of symptoms commonly found in older cancer survivors. Most of the studies use comorbidities as a demographic variable for descriptive correlational information instead of a major study

variable of interest.

Implications for Interprofessional Care and Research

Clinicians in cancer care are often presented with challenging patient care situations that include normal physiological and psychological changes with age, multiple comorbidities and chronic conditions and their treatments, and complex social situations. Comprehensive, multidimensional care incorporates a patient's past and current health care experiences and plans for future issues in cancer survivorship. Understanding the interrelationship between the cancer experience in older adults, acute and chronic symptoms, and cancer as a chronic illness is essential in coordinating ongoing care for this complex population. In addition, understanding the origins of symptoms in the older adult may be significant in the development and implementation of tailored interventions for symptom management in this population. The distinction between the disease process, treatment side effects, and the normal physiological changes of aging may guide individual health-behavior choices.

During the diagnosis and treatment phase, cancer is often viewed as an acute illness; however, this view may change in the posttreatment phase. Coordination of care of cancer survivors as they transition to their primary care provider is also challenging, depending on the patient's circumstances and the impact of cancer and its treatment on other chronic illnesses (Hewitt, Greenfield, & Stovall, 2006). In addition, the patients' perceptions of cancer as a chronic illness have the potential to reshape the care plan for the general health and wellness of older cancer survivors. Long-term cancer-survivorship care plans may facilitate the care transition from oncologist to primary care physician, and may serve as a foundation for healthy aging while incorporating cancer into the

survivor's personal health history of chronic conditions (Hewitt et al., 2006).

One interesting area for further study is the concept of chronic illness burden and symptom perception in cancer survivorship. Older adults translate chronic illness and symptoms within a context of prior experiences with health and illness, perceptions of illness and symptoms, and general perceptions and expectations of aging (Williamson & Schulz, 1995). It is also important to consider the generational cohort effect on healthy aging as individuals become more educated about health promotion, disease prevention, and healthy aging behaviors. Another issue that needs further exploration is that of perception of comorbidity burden prior to cancer diagnosis and during the immediate posttreatment and long-term survivorship periods, and its impact on overall quality of life in older adult cancer survivors.

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CHAPTER 5

DEVELOPMENT OF A SELF-REPORT TOOL FOR MEASURING COMORBIDITY BURDEN AND SYMPTOM PERCEPTION IN OLDER ADULTS WITH CANCER

Abstract

One third of all cancers are diagnosed in older adults (aged 65+). The diagnosis often co-occurs with normal and pathological changes of aging that include chronic diseases and related symptoms. Individual perception of the impact of chronic illness and symptoms may have a profound effect on the health care choices of an older adult. The Comorbidity and Symptom Measurement in Oncology Scale (COSMOS) is a newly developed self-report tool for measuring comorbidity burden and symptom perception in the oncology population. It is projected that COSMOS could be easily used in the clinical setting as an integral component of the comprehensive geriatric assessment of older adults with cancer. This chapter describes the initial development of the COSMOS using a multistep approach to determine content validity, beginning with a thorough review of relevant literature. A panel of six expert clinicians and researchers in geriatric oncology and symptom management participated in a survey with both quantitative and qualitative items for evaluation of the content validity of the COSMOS. Interrater agreement for

item and subscale relevancy was calculated using the content validity index (CVI) and Interclass Correlation Coefficient (ICC) statistic. General scale revisions included retaining items with an item CVI of $\geq$.80 and ICC$\geq$.60. In addition, qualitative comments from the expert reviewers were used to clarify specific items in each subscale. This chapter discusses the process and results for determining content validity for a newly developed scale, COSMOS, and finalizing the scale for pilot testing with the target population.

Introduction

Older adults with cancer comprise more than two thirds of the cancer population, and it is estimated that older adults with cancer have an average of two to four comorbidities (Cohen, Lan, Archer, & Kornblith, 2012; Howlander et al., 2015). The most common comorbidities in older adults are arthritis, cardiovascular disease (heart disease and hypertension), diabetes, and chronic respiratory diseases (Federal Interagency Forum on Age-Related Statistics, 2012; Vaeth, Satariano, & Ragland, 2000). The symptom experience in older adults with cancer is often complex and includes symptoms related to cancer, its treatment, and chronic conditions. Normal expectations of aging include both the development of chronic conditions and symptoms that may affect physical and emotional functioning (Repetto et al., 1998; Williamson & Schulz, 1995). There are several valid and reliable measures of comorbidities in adult populations, but currently, few tools are available to measure comorbidity burden via self-report (DeGroot, Beckerman, Lankhorst, & Bouter, 2003; Extermann, 2000; Katz, Chang, Sandha, Fossel, & Bates, 1996). In addition, there are multiple tools available to assess symptoms using self-report, some of which target specific populations.

Existing measures have not provided an easy way to link symptom measurement with measurement of comorbidity burden. Another gap has been the inability to measure symptom attribution. Thus, if a patient reports pain, it is difficult to know whether the pain is related to cancer, another chronic illness, or physical changes associated with aging. The use of a self-assessment scale that combines comorbidity burden and symptom perception may facilitate communication between cancer survivors and the health care team, leading to holistic and comprehensive symptom management that is patient centered and enhances quality of life.

Purpose

The purpose of this study was to describe the initial development and content validity of a self-report scale for measuring comorbidity burden and symptom perception: the COSMOS. This tool combines a self-report assessment of a broad range of comorbidities commonly found in older adults, such as cardiovascular, renal, gastrointestinal, hepatic, endocrine, and neurological disease processes and their impact on daily life, with a comprehensive symptom-perception assessment. The juxtaposition of reported comorbidities and symptom assessment provides the older adult with an opportunity to consider symptoms within the context of his or her current health, inclusive of comorbidities, cancer diagnosis, treatment, and perceptions of the aging process. The assessment of comorbidity burden and symptom perception has the potential to facilitate focused, timely care for cancer survivors. This assessment may also be valuable for facilitating communication between cancer survivors and their primary care providers as they transition from the acute treatment of cancer to long-term follow up. The COSMOS provides a patient-focused view of physical or psychological issues,

which may have an impact on the patient's quality of health care and overall life quality.

Background

COSMOS was based on a blended conceptual model developed from the Theory of Unpleasant Symptoms (TOUS; Lenz, Pugh, Milligan, Gift, & Suppe, 1997) and the Common Sense Model (CSM; Prohaska, Keller, Leventhal, & Leventhal, 1987; Ward 1993). The model, depicted in Figure 5.1, provides a conceptual basis for the constructs of comorbidity burden and symptom perception. Comorbidity burden is defined as a combination of the presence of chronic illness and the interference of each illness with general daily life. The construct of symptom perception is multidimensional and includes symptom presence, symptom bother, and the client's perception of the cause of the symptom. Identification of the perceived cause of each symptom links chronic illness, cancer, their treatments, and aging as possible considerations for interpretation of the meaning of a symptom or group of symptoms. This knowledge can better facilitate implementation of a key guiding principle in symptom management: Treat the cause.

TOUS is a middle-range theory describing both the antecedents and sequelae of unpleasant symptoms such as cancer-related fatigue or pain (Lenz et al., 1997; Lenz, Suppe, Gift, Pugh, & Milligan, 1995). This theory incorporates three factors that influence symptom perception, including physiological, psychological, and situational factors. These three factors interact with each other and have a direct impact on the development and exacerbation of symptoms. Symptoms are also thought to occur in groups or clusters, to interact with each other and ultimately affect an individual's functional status, cognitive functioning, and physical performance. The effect of symptoms on overall performance, in turn, has an adverse impact upon the symptoms and

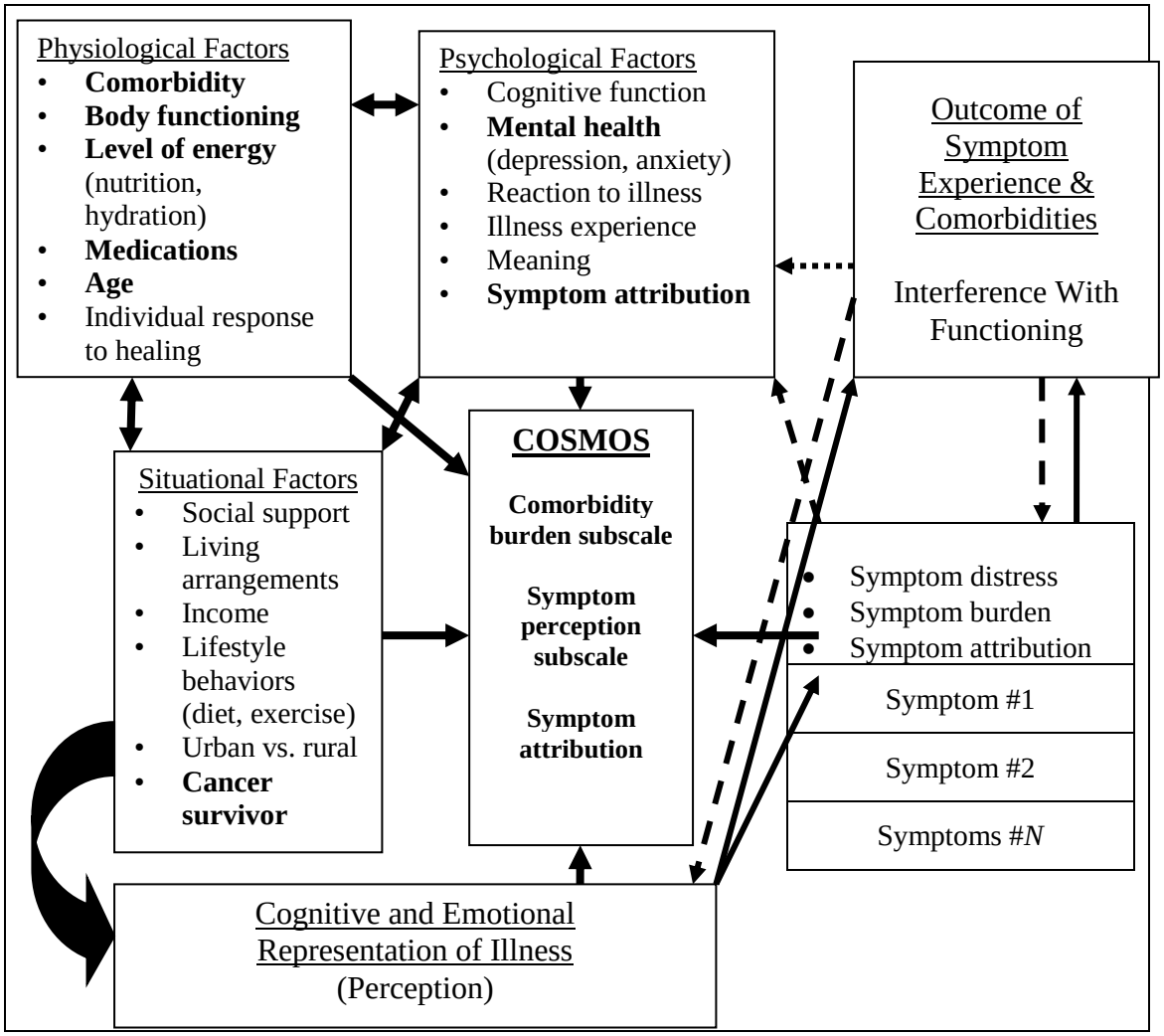

Figure 5.1 Relationship of COSMOS and conceptual model. Bolded words indicate dimensions of measurement.

factors that were antecedent to symptom development.

This model suggests that symptom-management interventions may be effective at the antecedent level to prevent or decrease symptom development or at the symptom level to prevent or decrease the impact of the symptoms on performance (Lenz et al., 1997). The presence of multiple comorbidities in the older adult with cancer may lead to the development of complex symptoms that can affect overall functioning and quality of life (Dodd, Miaskowsi, & Paul, 2001; Gift, Jablonski, Stommel, & Given, 2004).

An individual's interpretation of her or his symptoms can be comprehensively understood by using an information-processing model such as the CSM. This model proposes that people have specific ideas about their illnesses and that these ideas guide coping behaviors for health and illness (Haggar & Orbell, 2003; Leventhal, Meyer, & Nerenz, 1980; Ward, 1993). The CSM describes three stages of information processing, including cognitive and emotional representation of illness, coping with illness, and appraisal of the effectiveness of the coping strategy. This general framework integrates the physical, psychological, and social dimensions of symptom perception and subsequent choices of symptom-management actions. The distinction between the disease process, treatment side effects, and the normal physiological changes of aging may guide individual health-behavior choices.

The COSMOS subscales are based on a cancer survivor's perception of his or her chronic illnesses and symptoms within the context of past and present cancer experiences. The comorbidity burden subscale measures the presence of chronic illness and the impact or burden on daily life. The symptom perception subscale measures the presence of symptoms and the overall impact of each symptom on daily life. Symptom

perception includes symptom distress, duration, intensity, and attribution. Individuals may consider physiologic, psychological, and situational/social factors as they think about the impact of chronic illness and symptoms on their experience as a cancer survivor.

Methods

Overview of Scale Development

Development of a measure for a complex phenomenon requires a rigorous and organized approach. Lynn (1986) suggested using a two-stage process including the developmental stage and the judgment-quantification stage. The developmental stage includes three steps: (a) identification of the content domain, (b) item generation to fully represent the essential areas within the domain, and (c) assembly of generated items into a usable form for piloting with a target population. The judgment-quantification stage includes using a panel of experts to evaluate each item and the instrument for relevancy and representativeness of the domains being measured. This process is similar to the eight-step process outlined by DeVellis (2003), which also includes conducting a pilot of the scale in a representative sample population, evaluating items based on pilot data, and optimizing scale length.

The determination of validity is a critical step in the development of relevant and accurate measures of complex clinical phenomenon. Content validity can be defined as the extent to which a measure reflects a specific content domain (Carmines & Zeller, 1979; DeVellis, 2003). The determination of content validity includes a comprehensive review of literature relevant to the phenomenon of interest, clear definitions of the constructs being measured, and exploration of relevant theories that add clarity to the

defined construct (DeVellis, 2003).

Developmental Stage

COSMOS was initially developed by the investigator based on an extensive review of relevant literature on comorbidity assessment, symptom assessment, and symptom attribution. The scale was conceptualized to include two components, the comorbidity burden subscale (CoB) and the symptom perception subscale. The CoB is based on a comprehensive review of several well-established measures of comorbidity, including the Charlson Index (Charlson, Pompei, Ales, & MacKenzie,1987; Charlson, Szatrowski, Peterson, & Gold, 1994), Cumulative Illness Rating Scale–Geriatric (Extermann, Overcash, Lyman, Parr, & Balducci, 1998; Guralnik, 1996; Miller et al., 1992), Index of Coexistent Disease (Imamura, McKinnon, Middleton, & Black, 1997), Life Threat Risk Scale (Yancik et al. 1996; Yancik & Wesley, 1998), and Charlson Self-Report Questionnaire (Katz et al., 1996). A brief description of each comorbidity measure can be found in Table 5.1.

The first version of the CoB subscale was a 37-item checklist comprised of yes/no questions to assess the presence of a chronic disease or chronic condition and the impact of the chronic illness on the patient's daily life, with possible responses ranging from "not at all" to "a great deal." The scale had 33 items focused on physical illness or chronic conditions and four items focused on cognitive or psychological conditions. The initial CoB subscale had a Flesch Reading Ease score of 66 and a Flesch-Kincaid Grade Level of 6.4 as measured by the Flesch-Kincaid Readability Scale (Paz, Liu, Fongwa, Morales, & Hays, 2009).

The initial version of the symptom perception subscale (SxP) was based on a

Table 5.1

Select Measurement Scales for Comorbidity in Oncology Populations

Measure	Description
Charlson Index	Predicts mortality risk over a period of a few weeks to 10 years in a broad range of diagnoses by rating 19 diseases with a weighted scoring system (1–6 points) Data collection method: Medical record review (Charlson, Pompei, Ales, & MacKenzie,1987; Charlson, Szatrowski, Peterson, & Gold, 1994)
Charlson Self-Report	Evaluates the presence of disease and severity of current comorbidities using a simple 10-item questionnaire with a combination of yes/no and multiple-choice questions Data collection method: Self-report (Katz, Chang, Sandha, Fossel, & Bates, 1996)
Cumulative Illness Rating Scale–Geriatric	Evaluates 14 body systems using a weighted scoring system (0 = no impairment to 4 = life threatening) on a 7-point Likert scale Data collection method: Medical record review (Extermann, Overcash, Lyman, Parr, & Balducci, 1998; Guralnik, 1996; Miller et al., 1992
Index of Coexistent Disease	Rates 13 categories of comorbid diseases with 2 different dimensions: Index of Disease Severity (Grade 0 = no coexistent disease to Grade 3 = uncontrolled disease that causes moderate to severe disease symptoms) and Functional Severity (Level 0 = normal function to Level 2 = serious impairment); total scores based on an explicit list of symptoms, signs, and laboratory tests Data collection method: Medical record review (Imamura, McKinnon, Middleton, & Black, 1997)
Life Threat Risk Scale	Measures the potential impact of 35 comorbid conditions on short-term survival of the individual using a 0–3 scale (0 = negligible to 3 = high) Data collection method: Medical record review (Yancik et al., 1996; Yancik & Wesley, 1998)

comprehensive review of the most prevalent symptom-assessment tools being used in clinical oncology research, including the Edmonton Symptom Assessment Scale (Bruera, Kuehn, Miller, Selmser, & Macmillan, 1991; Chang, Hwang, & Feuerman, 2000; Jenkins, Schulz, Hanson, & Bruera, 2000; Philip, Smith, Craft, & Lickiss, 1998), M. D. Anderson Symptom Inventory (Cleeland et al., 2000), Memorial Symptom Assessment Scale–Short Form (Chang, Hwang, Feuerman, Kasimis, & Thaler, 2000; Portenoy et al., 1994), Rotterdam Symptom Checklist (de Haes, van Knippenberg, & Neijt, 1990), and Symptom Distress Scale (Degner & Sloan, 1995; McCorkle & Benoliel, 1983; McCorkle & Young, 1978; Munkres, Oberst, & Hughes, 1992).

A brief description of each symptom measure can be found in Table 5.2. After consideration of the format and symptom lists of the most commonly used oncology assessment tools, the symptom perception subscale was adapted (with permission) from the Memorial Symptom Assessment Scale–Short Form (MSAS-SF; Chang, Hwang, Feuerman, Kasimis, et al., 2000). The content of this scale was further validated by comparing it to a list of symptoms that accompany the most prevalent cancers within the older adult population, including lung, breast, prostate, colorectal, pancreatic, bladder, and ovary cancers, and leukemia and non-Hodgkin's lymphoma (American Cancer Society, 2015).

Version 1 of the SxP included three dimensions for each symptom: presence of physical or psychological symptoms, symptom bother, and perceived cause of current symptoms. The symptom-presence dimension had 34 items (28 physical symptoms and 6 psychological symptoms). The symptom-bother dimension was a three-point Likert scale that was designed to measure symptom distress or bother. The symptom bother scale was

Table 5.2

Select Measurement Scales for Symptoms in Oncology Populations

Measure	Description
Edmonton Symptom Assessment Scale	Measures current symptom levels of nine symptoms using a visual analogue scale (0–100mm) Data collection method: Self-report (Bruera, Kuehn, Miller, Selmser, & Macmillan, 1991; Chang, Hwang, & Feuerman, 2000; Philip, Smith, Craft, & Lickiss, 1998)
M. D. Anderson Symptom Inventory	Measures presence and severity on a 0–10 scale for 13 symptoms; also includes a six-item symptom-interference scale Data collection method: Self-report (Cleeland et al., 2000)
Memorial Symptom Assessment Scale	Measures symptom presence of 32 items and symptom distress of each using a five-point Likert scale; the scale includes three short-form subscales: high and low prevalence physical and psychological symptoms Data collection method: Self-report (Chang, Hwang, Feuerman, Kasimis, & Thaler, 2000; Chang et al., 1998; Portenoy et al., 1994)
Rotterdam Symptom Likert Checklist	Measures symptom presence and bother using a four-point scale (0 = not bothered at all to 4= bothered very much) Data collection method: Self-report (de Haes, van Knippenberg, & Neijt, 1990)
Symptom Distress Scale	Measures 13 items on a five-point Likert scale for symptom distress Data collection method: Self-report (Degner & Sloan, 1995; McCorkle & Benoliel 1983; McCorkle & Young, 1978; Munkres, Oberst, & Hughes, 1992)

collapsed from the original five-point scale in the MSAS-SF to simplify the scale for clinical use. The symptom attribution subscale is a five-point categorical scale that describes the cancer survivor's perceptions about the cause of each symptom, including aging, cancer, cancer treatments, medications for noncancer conditions, and other causes. In addition to the symptom list, there was a space for participants to add and evaluate other symptoms they were experiencing that were not on the list. The initial SxP had a Flesch Reading Ease Score of 84 and a Flesch-Kincaid grade level of 4.2.

COSMOS was developed for a target population of older adults (>65 years) with cancer, other comorbidities, and symptoms. Self-report symptom scales have been reported as being useful and reliable in oncology populations (Ingram et al., 2002; Silliman & Lash, 1999; Tishelman, Taube, & Sachs, 1991). Throughout the development stages of the COSMOS, several population-specific considerations were taken into account, such as physiological changes of aging, measurement burden, "test anxiety," decreased clarity of thought with complex concepts, and visual acuity (Burnside, Preski, & Hertz, 1998; Ingram et al., 2002; Rasin, 2004). COSMOS (version 1) was formatted in a concise grid that included a simple checklist and check-box approach. The COSMOS had a simple construction, with mostly dichotomous rating scales, easy readability, and simple instructions. It was anticipated that the scale could be read easily with the 12-point font and a high contrast print of black lettering on a white background. The estimated time for completion of both the CoB and SxP was about 15 to 20 minutes. The scale was designed to be completed by cancer survivors themselves, or could be read and recorded by an assistant if the patient had physical limitations such as impaired sight or grip strength that prevented physical completion of the tool. It was anticipated that cancer

survivors with mild cognitive impairment would need some assistance in completing the tool.

Judgment-Quantification Stage

The process for selecting a panel of content experts was based on recommendations outlined by Grant and Davis (1997) and Lynn (1986). Following study approval by the University of Utah Institutional Review Board, 12 potential expert clinicians and researchers were identified by the author based on the following inclusion criteria: (a) clinical practice or research expertise in oncology or gerontology/geriatric oncology care and symptom management, (b) publications within their specialty area in refereed journals (≥3 publications), and (c) national presentations in their area of expertise (≥2). Experts were identified through gerontology and oncology specialty-organization contacts and literature searches for publications listed in traditional health care literature databases. Every effort was made to recruit expert panelists from a variety of geographical areas in the United States. Potential expert panelists received an invitation to participate in the evaluation of the content of the COSMOS subscales using a standardized letter delivered via email. The invitation explained the purpose of the study, the expert's role within the study, and the expected time frame of the study.

When a panelist agreed to participate within the specified time frame, an expert panel packet including the following items was sent to them via email, and they were given 4 weeks to return their responses:

- An introduction letter to the study;
- A brief description of the tool, its content domains, the objectives for tool construction, and a definition of terms;
- Specific instructions and guidelines for study participation and data collection;

- A copy of the original scale (COSMOS); and
- A copy of the scale for rating relevancy of each item and a comment field for each item.

Each participant on the panel of experts used a critique form to record item relevancy and overall instrument relevancy for COSMOS. A four-level Likert-type rating scale was used for ratings of relevancy of the items, as outlined in Table 5.3 (Lynn, 1986).

In addition, each expert panelist was asked to comment on specific aspects of the overall tool, such as clarity of instructions, time frames of patient experiences, and critical omissions from each subscale, and to offer suggestions for specific-item revision and scale format and general overall comments about the scale. Reminder emails were sent to expert panelists at 2 and 4 weeks after the initial email with the content validity packet.

All data were entered into two parallel but separate databases and then compared for accuracy; any mismatched data were compared with the original data and reentered. Qualitative data were derived from expert panelists' written comments and analyzed for common content. Similar suggestions were made for the CoB and SxP regarding

Table 5.3

Rating New Item Relevancy

Rating	Description
1	Not relevant
2	Unable to assess relevance without item revision OR item is in need of such revision that it would no longer be relevant
3	Relevant but needs minor alteration
4	Very relevant and succinct

Adapted from Lynn, 1986, p. 384.

clarification of directions within the survey format and suggestions for simplifying the format.

Data for each subscale were analyzed using descriptive statistics and by calculating the CVI and ICC for each item, each subscale in general, and the instrument as a whole. The CVI is defined as the proportion of experts who rate an item as "3" or "4" on the relevancy rating scale previously defined (Lynn, 1986; Waltz, Strickland, & Lenz, 1991). For example, if five out of six experts rate an item as "3" or "4," the CVI for that item is .83, which is the minimum level required to establish content validity at the .05 significance level (Lynn, 1986). However, Polit, Beck, and Owen (2007) suggested that a CVI for an individual item within a scale of greater than .78 can be considered as excellent agreement, regardless of the number of expert raters. The CVI for the entire subscale is the proportion of content experts who judge the overall instrument as content valid (Lynn, 1986; Waltz et al., 1991).

A total ICC of agreement was calculated for the CoB and SxP and an individual ICC was calculated for each item within each subscale. The ICC has been defined as a special case of the weighted multirater kappa when rating categories are equally spaced along a single dimension (Fleiss & Cohen, 1973). The ICC (2,1) was chosen for this study, which reflects a two-way, random effects, absolute statistic. The interpretation of the multirater kappa coefficient and ICC are similar, and similar definitions and interpretations of values can be used (Fleiss & Cohen, 1973). The level of strength of agreement of ICC can be described as follows: a value of <.40 is considered poor strength of agreement, .40–.59 is fair strength, .60–.74 is good strength, and .75 and above is excellent strength (Cicchetti, 1984; Fleiss, 1971; Wynd, Schmidt, & Schaefer, 2003).

Tool revisions were based on the interrater agreement of the expert panel and their qualitative comments. Decision rules regarding items include the following:

- Items with CVI ≥.80 and ICC ≥.60 were retained for pilot testing.
- Items identified as having potential relevancy with CVI of .5–.79 were revised and incorporated into the tool.
- Items identified as omissions by ≥2 panelists were developed and added to the tool.
- Themes identified in the comments of ≥2 expert panelists were considered for incorporation into the revised tool prior to pilot testing.

Qualitative data such as comments on specific aspects of the overall tool, including clarity of instructions, time frames of patient experiences, critical omissions from each scale, suggestions for specific item revision, tool format, and general overall comments about the tool, were analyzed for themes to identify key critique elements based on the categories listed above.

Results

Seven out of the 12 experts contacted agreed to participate in the expert panel. The results of the expert panel are based on the 6 who completed the survey within the 1-month response time via email or facsimile communication. Five expert participants had more than 10 years of experience in oncology nursing and 1 had more than 10 years of experience in gerontology; 3 were advanced-practice clinicians and 2 were primary researchers; and 1 was active in both clinical practice and research. Four out of 6 panelists had specific expertise in gerontology or gero-oncology and 5 had specific expertise in symptom assessment and management. All panelists were affiliated with academic institutions as clinicians, faculty, or clinical researchers, and had more than 10 publications and presentations (combined).

The evaluation of the content validity results was based on the absolute responses of 6expert panelists using both the CVI and ICC. The CVI was calculated using the number of experts who rated an item as "relevant but needs minor revision" or "very relevant and succinct" divided by the total number of experts who rated the item. The minimal criteria for retaining each item was a CVI of $\geq$.83 (an agreement of 5 out of 6 expert panelists) with $p<.05$ and an ICC$\geq$.60. Of note, a CVI of .80 was used for two items that were answered by only 4 experts. Table 5.4 is a composite of CVI data for the CoB and Table 5.5 is a composite of CVI data for the SxP.

Comorbidity Burden Subscale

Thirty-seven items were evaluated by the expert panel and five items had a CVI <.80. These items included trouble moving one side of the body, dialysis or kidney transplant, lupus, behavior problems, and gall bladder and pancreas problems. The initial average measures ICC for the subscale was .972 (p = .000). The average CVI of the CoB was .798. Several items were suggested for inclusion in the CoB, including incontinence, chronic obstructive pulmonary disease (COPD), asthma, forgetfulness, and reproductive-related issues such as menopausal symptoms, prostate problems, and ovary or uterus problems. Qualitative comments focused on clarifying language for describing specific comorbidities in layman's terms, clarifying directions within the survey format, and suggestions for simplifying the format.

Symptom Perception Subscale

Thirty-four items were evaluated and 33 items were rated with a CVI $\geq$.80. One item (hot flushes) was rated with a CVI <.80. The average measure ICC for the

Table 5.4

Content Validity for Single Items Within the Comorbidity Burden Subscale

Subscale Item	No. of Raters Who Scored Item as Relevant/No. of Total Raters	Content Validity Index
Stroke	6/6	1.0
Heart attack	5/6	0.83
Arrhythmias	5/6	0.83
Blood clot	5/6	0.83
Stomach ulcer	5/6	0.83
Liver problems	5/6	0.83
Bowel problems	5/6	083
Diabetes/high blood sugar	5/6	0.83
Thyroid problems	5/6	0.83
Kidney trouble	5/6	0.83
Brittle bones/osteoporosis	5/6	0.83
Arthritis	5/6	0.83
Overweight by 50 pounds or more	5/6	0.83
Depression	5/6	0.83
Anxiety	5/6	0.83
Cancer (more than one type)	5/6	0.83
Poor blood flow in arms and legs	5/6	0.83
Trouble breathing while sitting	5/6	0.83
Trouble breathing while moving	5/6	0.83
General breathing problems	5/6	0.83
Severe indigestion at bedtime	5/6	0.83
Long periods of forgetfulness	5/6	0.83
Shuffling gait/trembling hands	5/6	0.83
Broken bones	5/6	0.83
Vision problems	5/6	0.83
Hearing problems	5/6	0.83
Balance problems	5/6	0.83
Multiple infections	5/6	0.83
Bleeding problems	5/6	0.83
Anemia	5/6	0.83
High blood pressure	4/5	0.80
Heart failure	4/5	0.80
Problem with gallbladder or pancreas	4/6	0.67
Trouble moving one side of body	4/6	0.67
Dialysis/kidney transplant	4/6	0.67
Lupus	4/6	0.67
Behavior problems	1/6	0.17

Note. Average content validity index for total subscale = 0.798.

Table 5.5

Content Validity for Single Items Within the Symptom Perception Subscale

Subscale Item	No. of Raters Who Scored Item as Relevant/No. of Total Raters	Content Validity Index
Difficulty concentrating	5/5	1.0
Trouble remembering	5/5	1.0
Pain	5/5	1.0
Lack of energy	5/5	1.0
Cough	5/5	1.0
Dry mouth	5/5	1.0
Nausea	5/5	1.0
Feeling drowsy	5/5	1.0
Numbness/tingling in hands and feet	5/5	1.0
Difficulty sleeping	5/5	1.0
Feeling bloated	5/5	1.0
Problems with urine	5/5	1.0
Vomiting	5/5	1.0
Shortness of breath	5/5	1.0
Sweats	5/5	1.0
Hot flashes	5/5	1.0
Problems with sexual interest	5/5/	1.0
Itching	5/5	1.0
Lack of appetite	5/5	1/0
Dizziness	5/5	1.0
Difficulty swallowing	5/5	1.0
Mouth sores	5/5	1.0
Taste changes	5/5	1.0
Weight loss	5/5	1.0
Hair loss	5/5	1.0
Constipation	5/5	1.0
Diarrhea	5/5	1.0
“I don’t look like myself”	5/5	1.0
Worrying	5/5	1.0
Feeling irritable	5/5	1.0
Feeling anxious	5/5	1.0
Feeling nervous	5/5	1.0
Changes in skin	4/5	.08
Hot flushes	3/5	0.6

Note. Average content validity index for total subscale = 0.98.

SxP was .843 (p = .000). The SxP CVI was .98. Only 5 expert panelists provided ratings on each item in this subscale, with a high level of agreement for most items. One panelist provided only qualitative data that were incorporated into the subscale revisions. Two expert panelists including “feeling sad or blue” or “hopelessness and helplessness” suggested one item for inclusion in the subscale. Qualitative comments focused on clarifying language for several symptoms, including changes in skin, pain, sleep-related symptoms, feeling bloated, problems with urination, sweats, and sexuality related symptoms. Similar suggestions were made for the CoB regarding clarification of directions within the survey format and suggestions for simplifying the format.

General Scale Revisions

Several reviewers (4/6) commented that the original grid format was too complex for older adults to navigate without becoming confused or frustrated. One major revision of the COSMOS scale was formatting, with minor content adjustments. A second review by the expert panel was deferred based on the high level of agreement about vague items and consistent suggestions for minor revisions.

Discussion

Data were analyzed using the item–content validity index, the scale average–content validity index, and the ICC for each item to control for the limitations of using either statistic alone. Both the CVI and ICC results were used to inform decisions about the final content to include in each subscale of COSMOS.

Comorbidity Burden Subscale

Based on the results from the expert panel, three items were deleted, two items were revised to improve language clarity, and three items were added. Based on the criteria of a CVI less than .80, indicating low rater agreement on item relevancy, the items behavior problems, dialysis, and lupus were deleted. The average measures ICC was .974 (p = .000) for the revised subscale with deleted items. This result reflects a strong level of agreement regarding item relevancy for the subscale and supports content validity. In addition, language was clarified on several comorbidity items based on the experts' feedback, including items related to cardiac disease, bone health, joint replacements, ulcers, and liver disease. Additions were made based on comments from the expert panel, including the following: Symptom-related breathing questions were replaced by specific questions about asthma and COPD, separate questions were developed for chronic gallbladder and pancreas issues, and language was clarified for specific chronic illness questions. In addition, the language in the instructions for the subscale was clarified. All changes in language for original and additional questions were generated by suggestions from at least 2 expert panelists. A major change was made from a complex, grid-like format of the original scale to a straightforward format, as illustrated in Figure 5.2. This change was based on comments made by expert panelists and endorsed by select experts in gerontologic research via personal communication. The simplified format incorporated many of the general principles for conducting research with older adults and yielded a Flesch-Kincaid readability level at the 3.9 grade level.

3. Have you ever had an irregular heartbeat that needed medications or a pacemaker? _____Yes _____No **If you answered yes**, please answer the question on the right. →	How much does this affect your current daily life? (Check **one**.) □ Not at all □ A little □ Some □ A great deal

Figure 5.2 Comorbidity burden subscale, revised format. (Sample item.)

Symptom Perception Subscale

The results from the expert panel rating validated the relevancy of 33 of the original 34 items, with CVI ≥.80. These items were retained and one item (hot flushes) was combined with hot flashes at the suggestion of 3 out of 6 reviewers. The average measures ICC was .884 (p = .0001) for the revised subscale. Overall results from the expert panel data support content validity of the SxP. One item, "feeling sad or blue," was added to the list of symptoms based on suggestions from the expert panel. Also based on their suggestions, one combination item was formed that included worrying, feeling anxious, and feeling nervous. In addition, language was clarified for several symptom descriptions and instructions for completing the subscale. The SxP was also reformatted, as illustrated in Figure 5.3. As in the case of the CoB, this change was made to simplify the format for older adults and was endorsed by select experts in gerontologic research. Overall, 31 items were retained unchanged, one item was added, and three items were merged with similar items.

Initial Scoring Guidelines

The CoB score consists of the self-reported presence of chronic illness and its effect on daily life. One point is assigned for each reported comorbidity and zero to four

3. **During the past month**, have you had pain? _____Yes _____No **If you answered yes**, please answer the questions on the right. →	3b. How much does this symptom bother you? □ None OR a little □ Some □ A great deal 3c. Check any of the following statements that you think are true about your symptom of pain. ___It is caused by aging. ___It is caused by my cancer. ___It is caused by my cancer treatments. ___It is caused by my medicines for noncancer conditions. ___This symptom has some other cause. (Write in what you think is causing the symptom.)

Figure 5.3 Symptom perception subscale, revised format. (Sample item.)

points are added based on the reported effect of the comorbidity on the individual's life. The higher the score for this subscale, the higher the comorbidity burden. The SxP score includes self-reported symptom presence and symptom bother. One point is assigned for symptom presence and zero to two points are added based on symptom bother. The higher the score for the symptom scale, the more intensely the symptom is perceived by the participant. Symptom attribution is constructed as a simple description of the perceived cause of each symptom by the participant. Participants were instructed to choose any of the five perceived causes for each symptom listed.

Limitations

There were several challenges in the development of the COSMOS subscales and their scoring. One issue was the identification of the most relevant and appropriate chronic illnesses to assess in older adults using a self-report instrument. The use of standard language when asking about the presence of certain chronic illnesses or chronic

health conditions may have an impact on the participant's response and the outcome of the CoB. Chronic illnesses may be described with specific diagnostic labels or symptom-related language, and may blur the lines between comorbidity and symptom assessment. The issue of clear, concise formatting for an older adult population was addressed by the expert panel's opinions and suggestions. Theoretical concepts were also considered regarding the intersection of chronic illnesses and their symptoms with cancer-related symptoms and the best method to assess this intersection. Another issue that was raised by the expert panel was the fundamental overlap between a chronic illness and a chronic symptom, such as pain or depression.

Statistical analysis for determining content validity was carefully considered to prevent inherent limitations of using one specific method to determine item relevancy for each subscale. A limitation of using the CVI alone is that it simply reflects the proportion of agreement without accounting for expert panelists' agreement by chance. An attempt to control for this limitation is to use a conservative number of expert panelists and analyze all rating categories separately. An additional measure of agreement, such as the ICC, can also be used. It is suggested that the ICC has several limitations, such as restricted information for evaluating individual items and individual feedback from expert panelists (Polit et al., 2007). Another potential limitation of using the ICC alone is the possibility of obtaining a high level of agreement in situations in which content validity is low (Polit et al., 2007). Using both statistical methods for evaluating content validity of a newly developed instrument adds to the strength of each subscale.

Implications

COSMOS version 2 (v2) was pilot tested with a target population of older adults with cancer, chronic illnesses, and symptoms to assess initial construct validity, reliability, and issues involved in scale completion (Lacasse, 2016c). Further revisions will be considered based on the results of pilot testing. Once initial validity and reliability are examined, it is envisioned that this scale may be used as a component of comprehensive geriatric assessment in oncology patients and may assist in targeted assessment of the impact of comorbidities and symptoms on overall functioning. In addition, the symptom attribution information may help clinicians integrate a targeted assessment and intervention approach to cancer survivors with specific comorbidities and symptoms. It also may be useful in the research setting as a basis for evaluating and predicting health-related outcomes for older adults with cancer and complex cancer symptom management. COSMOS results may also assist in the assessment of quality-of-life dimensions in cancer survivors related to the impact of comorbidity burden and symptoms perception in the context of an individual's current state of health and wellness.

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CHAPTER 6

COMORBIDITY AND SYMPTOM MEASUREMENT IN ONCOLOGY SCALE: INITIAL PSYCHOMETRIC RESULTS

Abstract

Older adults aged 65 years or older comprise more than 50% of cancer survivors. The diagnosis of cancer often co-occurs with other chronic illnesses and expected physiologic changes of aging. Perceptions of symptoms in the context of aging and chronic illness may have a profound impact on the diagnosis, treatment, and symptom-management outcomes of cancer survivors. The purpose of this study was the initial evaluation of the psychometric properties of a newly developed self-report tool for measuring comorbidity burden and symptom perception, the Comorbidity and Symptom Measurement in Oncology Scale (COSMOS). Following a study to establish content validity, the revised COSMOS (COSMOS v2) was pilot tested using a mixed-methods approach with a convenience sample of 62 cancer survivors aged 65 years or older with two or more comorbidities, one or more symptoms, and the ability to read and speak English. Participants were stratified into those on active cancer treatment (n = 32) and those off treatment for 1 year or more (n = 30). Each participant completed a paper-and-pencil version of the COSMOS v2 research packet. A subset of 7 participants was

interviewed to explore their experience with the COSMOS v2 and their perceptions about symptoms. Initial psychometric results indicate that the COSMOS v2 discriminates between cancer survivor treatment groups. Significant differences were found between treatment groups, with the off-treatment group having more comorbidities, such as osteoporosis and thyroid disease. There was also a difference between groups on the presence of specific comorbidities, as well as the presence and attribution of specific symptoms. Both subscales demonstrated strong test-retest reliability with the comorbidity burden subscale intraclass correlation coefficient (ICC) = .917 and the symptom perception subscale ICC = .696. There is evidence to support the validity and reliability of COSMOS v2 in a sample of older adult cancer survivors with multiple comorbidities and symptoms. COSMOS has potential for use in clinical practice, education, and research as a basis for patient-centered care management and optimizing quality of life in older adult cancer survivors.[1]

Introduction

Older adults are one of the most vulnerable and rapidly growing populations with cancer. Approximately two thirds of all cancers are diagnosed in individuals 65 years and older, and the diagnosis often co-occurs with the normal and pathological changes of aging, which include chronic diseases and conditions (Institute of Medicine[IOM], 2013). In an epidemiological study of more than 3,500 survivors of breast, prostate, lung, colorectal, and bladder cancers aged 60 years or older, it was found that 54.3% had two

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or more preexisting chronic conditions (Deckx et al., 2012). This study also compared chronic illnesses in cancer survivors and noncancer survivors and found that the most common illnesses in both groups were ischemic heart disease, hypertension, diabetes, lipid disorders, arthritis, low back pain, benign prostatic hypertrophy, dementia, and chronic obstructive pulmonary disease (COPD). The study also revealed that the presence of chronic illness in both groups was comparable, with the exception of venous thrombosis, which was significantly more prevalent in cancer survivors. In addition, previous reports of prevalent chronic diseases and conditions in geriatric cancer patients included gastrointestinal problems, thyroid dysfunction, and anemia (Vaeth, Satariano, & Ragland, 2000).

Comorbidity is associated with many sequelae that affect physical, mental, and social health outcomes, including functional impairment, symptoms, decreased mobility, anxiety, depression, and diminished social interaction (IOM, 2012; Valderas, Starfield, Sibbald, Salisbury, & Roland, 2009). Multiple site-specific physiologic effects have been identified in cancer survivors and can be considered as either immediate or late effects of specific therapies (Hewitt, Greenfield, & Stovall, 2006). Some of these late effects overlap with physiologic changes of aging and common comorbidities associated with an older age. Older adults may perceive symptoms as age-related and may learn to cope with chronic symptoms (such as pain and fatigue) as a normal part of the aging process. Some older adults with chronic illnesses may have different expectations regarding functional ability, and experience less overall symptom distress due to their frame of reference. The meaning of aging is very individual; normal symptoms are defined in the context of the unique individual and his or her distinctive life experiences and singular perception of

quality of life.

The role of multiple chronic conditions may be a significant factor in symptom perception and the impact of symptoms on the physical, psychological, and spiritual functioning of geriatric patients in all phases of the cancer disease trajectory. Although studies have shown that an increased number of comorbidities is associated with increased symptoms (Cella et al., 2010), the phenomenon of symptom perception in the older adult with cancer and multiple comorbidities has been minimally explored.

Measurement of Comorbidities and Symptoms in Cancer Survivors

There are several valid and reliable tools for measuring the burden of comorbidity that require a trained observer and chart review to extract data for comorbidity burden estimations. Tools commonly used to assess comorbidity include the Charlson Comorbidity Index, Cumulative Illness Rating Scale–Geriatric, Kaplan-Feinstein Index, and Index of Coexisting Disease (De Groot, Beckerman, Lankhorst, & Bowler, 2003; Extermann, 2000). The Charlson Comorbidity Index is the most widely used measure of comorbidity; it requires the use of a trained data collector to extract appropriate information from the medical record and code the data (Charlson, Pompei, Ales, & MacKenzie, 1987; Charlson, Szatrowski, Peterson, & Gold, 1994). A self-report questionnaire version of the Charlson Comorbidity Index also exists and is comprised of 10 main disease-oriented questions that assess the presence and severity of common comorbidities in older adults (Katz, Chang, Sandha, Fossel, & Bates, 1996). The Charlson Comorbidity Index assigns weights to diseases based on morbidity risk and excludes conditions that affect quality of life but have limited impact on morbidity. Current measures of comorbidity and comorbidity burden yield data focused on

physiologic burden and survival estimates that often inform treatment decisions for older adults with cancer; however, these measures lack the patient-centered perspective of burden of chronic illness on an individual's daily life.

Cancer-related symptoms have been studied for more than 20 years, but few studies have specifically focused on the older adult population of cancer survivors with multiple chronic illnesses. A small body of emerging evidence identifies the uniqueness of cancer-related symptoms in the geriatric population, the interrelationship among symptoms, and population-specific aspects of symptom assessment and management. There are several valid and reliable measurement tools available for assessing cancer-related symptoms, including the Symptom Distress Scale (Degner & Sloan, 1995; McCorkle & Young, 1978), Edmonton Symptom Assessment Scale (Bruera, Kuehn, Miller, Selmser, & Macmillan, 1991), Memorial Symptom Assessment Scale (Portenoy et al., 1994), Rotterdam Symptom Checklist (de Haes, van Knippenberg, & Neijt, 1990), and M. D. Anderson Symptom Inventory (Chang, Hwang, Feuerman, & Kasimis, 2000; Cleeland et al., 2000); however, there are no specific measures for the oncology, chronic illness, or aging population that integrate symptom presence, symptom perception, and symptom attribution. The coupling of symptom perception and symptom attribution provides clinicians with unique patient-centered perspectives for symptom assessment and intervention.

Older age may be related to increased physical symptoms mediated by an increased number of chronic illnesses (Kolk, Hanewald, Schagen, & Gijsbers van Wijk, 2003). A study of individuals aged 65 to 89 with advanced lung cancer receiving cancer therapies reported a statistically significant difference ($p<.004$) between symptoms

reported by those with one comorbidity (1.7 symptoms) and those with five or more comorbidities (>3.5 symptoms; Gift, Jablonski, Stommel, & Given, 2004). An interviewer-administered tool to measure specific comorbidities and their associated symptoms was developed by Crabtree, Gray, Hildreth, O'Connell, and Brown (2000). The Comorbidity Symptom Scale was developed based on interview data that incorporate the presence of 23 comorbidities and the severity of their associated symptoms in older adults. This scale allows the interviewer to obtain symptom data directly from the patient, but only comorbidity-associated symptoms are identified. This measure provides a general overview of specific comorbidities and their associated symptoms, but does not allow for assessment of multiple symptom attributions such as aging, cancer and its treatment, chronic conditions, and others.

The Symptom Bother–Revised Scale was developed by Heidrich, Egan, Hengudomsub, and Randolph (2006) to measure symptom distress related to 13 symptoms commonly reported by older adults with chronic illnesses or conditions. This scale has a reported reliability range of .78–.89 (alpha coefficient). Heidrich et al. (2006) used a revised version of this scale with a population of older women, including breast cancer survivors (n = 18) and those without breast cancer (n = 24). Half of the breast cancer survivors were reported to be on hormonal therapy at the time of the study. Participants reported on 37 symptoms common to the breast cancer survivor population, including symptom presence, level of distress, and perceived cause, including breast cancer, other illness, aging, or "don't know." The most frequently reported chronic illnesses across both groups were arthritis, cataracts, hypertension, osteoporosis, peripheral vascular disease, and depression. This study found that aging was the most

frequent perceived cause of symptoms, followed by chronic illness. A critical evaluation of the literature on cancer and comorbidity, measurement of comorbidity, cancer-related symptom measurement, and symptom appraisal revealed no self-report tools that measure the relationship between comorbidity burden, symptom perception, and symptom attribution (Lacasse, 2016b).

Methods

The purpose of this methodological study was to conduct initial psychometric testing of the COSMOS v2 and examine the feasibility of utilizing it with older adults with cancer and comorbidities. Specific aims of the study included the following: (a) determine the construct validity of the COSMOS v2 with known groups of older adults on active cancer treatment and off treatment; (b) determine initial test-retest reliability of the COSMOS v2 subscales in a group of older adults cancer survivors who have finished active cancer treatment; (c) determine the feasibility of a self-administered measurement tool of comorbidities and symptoms in a population of older adults with cancer, including completion time, response patterns, scale comprehension, missing items, and patterns in missing data; and (d) explore the relationship between comorbidities, symptoms, and general functioning. This study was designed to evaluate the initial validity, reliability, and feasibility of using a self-report method of determining comorbidity burden and symptom perception in older adult cancer survivors.

Participants

A convenience sample of 65 participants was recruited from several outpatient and community settings in the southwestern United States. Study eligibility criteria

included age≥65 years; cancer diagnosis for ≥2 months; ≥two comorbidities as confirmed by self-report; ≥one symptom as confirmed by self-report; and the ability to read, write, comprehend, and speak English. An initial subset of 39 participants was screened for intact cognition using the Mini Mental Status Exam (MMSE). A score of ≥23 was needed to qualify for the study. No potential participants in this initial group scored below 23, and some potential participants objected to the screening exam because they associated it with psychiatric and cognitive testing. This formal criterion was subsequently replaced by a determination of capacity to complete the instruments based on a preconsent telephone discussion that required following instructions to call the principal investigator. The discussion included appraisal of the responses of the potential participant to specific eligibility questions regarding age, cancer history, comorbidities, and symptoms for indication of cognitive dysfunction.

Both male and female participants were stratified into two groups according to treatment status: those in active treatment and those off treatment. Those currently undergoing active cancer treatment (surgery, chemotherapy, hormonal and/or radiation therapy) constituted the active-treatment group, and those who had completed any cancer treatment by 1 or more years constituted the off-treatment group. Recruitment extended over several years until at least 30 complete data sets were collected in each participant group. The variable most likely to show the impact of the time frame for recruitment is the treatment type and its associated treatment-related symptoms. During the recruitment period, cancer treatments shifted to an increase in targeted therapies for primary treatment and long-term secondary treatments; however, these therapies were not expected to have a significantly different symptom profile from traditional therapies.

Recruitment strategies included referrals from health care providers in cancer treatment clinics, community-based health care providers, community events for cancer survivors, cancer support groups, and distribution of flyers. Four hundred potential participants were initially screened based on age, cancer history, and treatment status between June 2010 and June 2015; 154 who met the initial screening criteria and expressed interest in the study were contacted by me for further screening. Ninety-six (62%) met full screening criteria and were invited to participate; 31 declined to participate due to time constraints, length of the survey packet, and decreased interest after further consideration. A total of 65 participants were consented. Sixty-two participants completed the comorbidity burden subscale (CoB) and 61 participants completed the symptom perception subscale (SxP). The first 17 participants in the off-treatment group were recruited for test-retest data collection, with a yield of 15 completed surveys. In addition, 7 participants were interviewed regarding their experience with completion of the COSMOS v2 and how they thought about chronic illness and symptoms.

Instrumentation

Comorbidity- and symptom-related data were collected using a newly developed COSMOS that uniquely combines a self-report assessment of a broad range of chronic illnesses and conditions commonly found in older adults with a comprehensive symptom-perception assessment. Initial content validity for COSMOS v1 was established for each subscale using an expert panel (Lacasse, 2016a).

COSMOS v2 includes a revised version of the CoB and the SxP. The CoB includes 38 chronic conditions and is comprised of two dimensions that assess the

presence of comorbidities and the effect of each comorbidity on daily life. Total scores range from zero for no comorbidities to 152. Higher scores indicate a higher comorbidity burden. The SxP includes 32 symptoms and is comprised of two dimensions that assess the presence of symptoms and their effect on daily life. Total scores range from zero for no symptoms to 96, with higher scores indicating higher symptom burden. The symptom attribution checklist is a five-category list designed to collect descriptive data on the participants' perceptions regarding the attribution of each symptom, including aging, cancer and cancer treatment, noncancer medications, and other explanations or a combination of attributions. These data inform the perception of each symptom.

In addition, the functional interference subscale of the Functional Performance Index was used to evaluate the overall effect of general health (inclusive of comorbidity and symptoms) on general functioning (Leidy, 1999). The functional interference subscale is a five-item summative scale, with each item rated on the amount of interference posed by current health on life functioning (Appendix I). The scores range from 1 to 30, with high scores indicating higher levels of functional interference. The functional interference subscale had a Cronbach's α of .79, indicating acceptable internal consistency reliability in this study sample.

A general information questionnaire (GIQ) was used to collect descriptive data on each participant, including demographics, self-reported cancer history, and current medications list. The medication count was used as a general measure of comorbidity. In addition, participants were asked to report their completion time for each subscale.

Interview Data

A small sample of participants was interviewed about their impressions of each subscale, including the clarity of instructions for each section, the length of each section, and the clarity of the questions in each section. In addition, participants were asked to indicate how they felt about each section, if the sections brought up questions about their own health, what they thought about before talking with health care providers about symptoms (including causality), and the effect of chronic illness on symptom appraisal.

Procedure

Study approval was granted by the University of Utah Institutional Review Board. After granting informed consent, eligible participants were asked to complete a data-collection packet in the following order: the COSMOS v2 subscales, functional interference subscale, and GIQ. All participants were assessed for their ability to complete the survey packet on their own. Two participants were unable to complete the survey packet independently; 1 was assisted by me and only completed the CoB subscale due to fatigue; another participant was assisted by a family member and completed the subscales in two separate sections for a total completion time of 59 minutes. Each participant who required assistance was judged to be cognitively able to respond to the surveys but physically frail. Fifteen participants in the off-treatment group were contacted by mail 2 weeks after the initial survey packet was completed and asked to complete the COSMOS v2 a second time to assess reliability and stability. In addition, a modified GIQ was used with the second administration of the COSMOS v2 to determine any individual changes that might affect the stability of the scale over the intervening time.

Statistical Analysis

Based on recommendations for initial instrument-development studies, a minimum of 30 participants were recruited for both the active-treatment and off-treatment groups. The literature on sample size for pilot studies for instrument development recommends a minimal sample size of 25 to 40 participants per known group (Hertzog, 2008; Johanson & Brooks, 2010). In addition, sample size calculations were explored for a power of .8 to detect a moderate effect size for differences between groups (Cohen's $d = .5$) and a small effect size (Cohen's $d = .3$) for symptom perception scores on comorbidity burden. Calculations indicated a need for a sample size of at least 64 participants per known group. It was recognized that while the actual sample size was not large enough to detect clinically meaningful differences between active-treatment and off-treatment groups, it was sufficient to assess feasibility and initial psychometric performance.

Analyses were conducted using SPSS® (version 23). Exploratory and descriptive statistics were used to analyze sample characteristics and initial COSMOS v2 data, including frequencies and proportions of participants experiencing each comorbidity and symptom. Differences between treatment status groups on categorical variables were analyzed using Pearson's chi square. Continuous data were analyzed using independent samples *t*-tests. Test-retest reliability for each subscale was analyzed using a two-way, random effects, absolute-agreement model of the intraclass correlation coefficient (ICC).

Each symptom was analyzed for its assigned attributes using frequencies and proportions as related to each specific symptom. Twenty-two different combinations of symptom attribution were reported. Symptom attributions were collapsed into three

clinically meaningful units of analysis, including age-related, cancer and treatment-related, and other causes (chronic conditions and medications). The symptom attribution data were analyzed based on treatment status using Pearson's chi square. Pearson correlation coefficients were used to assess the relationship between select continuous variables of CoB and SxP scores, the medication count, and the functional interference subscale score.

Due to the exploratory nature of the study, an a priori level of significance was set at .05. Interpretation of statistically significant results was carefully considered to avoid making a Type I error. Although consideration was given to setting the significance level lower, correcting for multiple statistical comparisons on a limited data set increases the likelihood of missing a statistically significant result (Type II error; Reid, 1983).

In addition, scale responses were analyzed for patterns of information related to instrument administration. Due to the nature of self-reporting, missing data were treated as an answer of "No" when reporting comorbidities and symptoms regarding the calculation of CoB and SxP scores. Each comorbidity and symptom was analyzed separately to minimize the effect of missing data on overall analysis.

A small convenience sample of 7 participants who consented to be interviewed were provided with a copy of the COSMOS v2 subscales and interviewed several weeks after completion of the survey packet. Participants were asked specific questions related to feasibility of the administration and content of each subscale. In addition, participants were asked to reflect on their symptom appraisal process in the context of their cancer history and chronic illness experience. Interviews were audiotaped by the principal investigator, transcribed, reviewed, and corrected. Participant responses were reviewed

for descriptive information specific to each subscale and descriptive statistics were used to analyze these data. Responses related to symptom appraisal were analyzed for themes that illuminate symptom perception and appraisal in the context of their cancer and chronic illness experiences.

Results

The 62 study participants included 32 on active treatment and 30 off treatment for 1 or more years; ranged in age from 65 to 90 years; were predominantly female and White non-Hispanic; were educated beyond the high school level; and were retired, living with a partner or spouse (Table 6.1). The off-treatment group had a greater proportion of females ($\chi^2 = 5.79$, $df = 1$, $p = .016$). Cancer-related participant data can be found in Table 6.2. There were differences between groups on several cancer-related characteristics, such as years of survivorship ($\chi^2 = 19.79$, $df = 3$, $p = .0001$) and type of cancer ($\chi^2 = 17.87$, $df = 2$, $p = .045$). The years of survivorship had a broad range in each group; however, the majority (78.1%) of the active-treatment group had 5 or fewer survivorship years, whereas the majority (70%) of the off-treatment group had 5 or more survivorship years. The active-treatment group had an even distribution of diagnoses between breast, prostate, and other types of cancer, whereas the off-treatment group included mostly survivors of breast cancer and small numbers of various other cancers. Prostate cancer survivors were underrepresented in the off-treatment group. Treatment status of the active-treatment group was described by a single treatment grouping, including recent surgery (up to 2 weeks postoperative), current chemotherapy (up to 4 weeks after treatment), current radiation therapy (up to 2 weeks after treatment), and current hormonal treatment (ongoing). Both the active-treatment and off-treatment groups had

Table 6.1

Summary of Participant Characteristics

Participant Characteristics	Active Treatment $n = 32$	Off Treatment $n = 30$	Statistic (*df*)	*p*
Age:				
M	71.6 years	72.7 years	$t = -.67$ (60)	.507
SD	6.2 years	6.5 years		
Range	65–90 years	65–90 years		
Gender: Female	47%	76.7%	$\chi2 = 5.79$ (1)	.016
Ethnicity: White non-Hispanic	100%	93%	$\chi2 = 2.14$ (1)	.144
Employment status:				
Retired	87.5%	70%	$\chi2 = 4.74$ (1)	.192
Employed full time	9.4%	10%		
Employed part time	3.1%	13.3%		
Living situation:				
Living with partner/spouse	68.8%	56.7%	$\chi2 = 4.44$ (4)	.349
Living alone	33.3%	21.9%		
Education level: Some college, or more	90.3%	84%	$\chi2 = 6.76$ (1)	.239

Table 6.2

Summary of Cancer-Related Participant Data

Participant Characteristics	Active Treatment	Off Treatment	Statistic (*df*)	*p*
Time since diagnosis:	(*n* = 32)	(*n* = 30)	$\chi 2 = 19.79$ (3)	.0001
Up to 1 year	56.3%	6.7%		
>1 year to 5 years	21.9%	23.3%		
>5 years to 10 years	9.4%	33.3%		
>10 years	12.5%	36.7%		
Type of cancer:	(*n* = 32)	(*n* = 30)	$\chi 2 = 17.87$ (2)	.045
Prostate	31.3%	6.7%		
Breast	31.3%	36.7%		
Other	37.4%[a]	56.6%[b]		
Multiple cancers (>1)	6.2%	23.3%		
Current treatment:	(*n* = 32)			
Surgery	6.3%	--		
Chemotherapy	9.4%	--		
Radiation therapy	53.1%	--		
Hormonal therapy	28.1%	--		
Cancer treatment history:				
Multimodality (two or more modalities)	100%	100%		
Functional interference score	(*n* = 31)	(*n* = 30)	*t* = 1.29 (60)	.221
	13.2	11.5		
	(*SD* = 5.9)	(*SD* = 4.6)		

[a] Other cancers include brain, skin, melanoma, lung, bladder, esophageal, lymphoma, and leukemia.
[b] Other cancers include melanoma, ovarian, sarcoma, renal, colorectal, lung, lymphoma, bladder, kidney, esophageal, and pancreatic.

history of two or more types of therapies, which is reflective of the general treatment history of cancer survivors.

Feasibility

The average time for completion of the CoB was about 9 minutes (range 3–25 minutes) and for the SxP was about 11 minutes (range 3–35 minutes). The average completion time for combined subscales was 19.5 minutes (range 7–50 minutes). There were no differences between groups with regard to completion times (Table 6.3).

No specific patterns of missing data were found for either subscale. Three participants missed a random page of the CoB, but each missed a different page. Several participants missed a random comorbidity and symptom question; however, no item was consistently skipped. In addition, when participants answered symptom bother and attribution questions without answering the symptom presence question, symptom presence was assumed for that symptom. Alternately, some participants answered a

Table 6.3

COSMOS Completion Times (Minutes)—Participant Self-Reported

Subscale, Mean, and Range	Participants on Active Treatment	Participants Off Treatment	*t* (*df*)	*p*
Comorbidity burden Subscale			-.24 (58)	.814
Mean completion time	8.9 min (5.2 min)	9.2 min (5.3 min)		
Range	3–20 min	3–25 min		
Symptom perception subscale			-.84 (55)	.405
Mean completion time	10.5 min (5.7 min)	12 min (7.4 min)		
Range	3–20 min	3–20 min		
Total Completion Time			-.43 (56)	.669
Mean completion time	8.9 min (9.7 min)	20 min (7.4 min)		
Range	7–45 min	7–50 min		

Note. min = minutes; *t* = independent samples *t*–test; *df* = degrees of freedom.

comorbidity question without answering the bother question. A maximum of 2 participants missed items for comorbidity or symptom presence, and a maximum of 4 participants missed a few symptom-bother items.

Data based on participant interviews indicated that the scale instructions were clear and straightforward to answer. All participants commented that the combined length of the subscales was too long. One out of 7 interviewed participants agreed that both subscales were more comprehensive than the checklists that they complete in their doctor's office. In response to the question of whether each subscale section brought up questions about their own health or symptom-appraisal process, participants generally agreed that reviewing the lists of comorbidities and symptoms was helpful and assisted in thinking about their own situation and how they thought about their symptoms. Each individual described his or her own symptom-appraisal process that included their personal history with cancer, chronic illness, and symptom experience within their unique survivor-centered social context. Four major sources were used for symptom appraisal, including (a) personal experience of symptoms from cancer and chronic illness; (b) personal body awareness; (c) family experience of symptoms from chronic illness, including cancer; and (d) health information from professional and public sources. A summary of interview data is presented in Table 6.4.

Comorbidity and Symptoms

Data were analyzed for differences in reported comorbidities and symptoms between the active-treatment and off-therapy groups. Table 6.5 includes data for the reported chronic illnesses and Table 6.6 includes data for the reported symptoms. The chronic illnesses or conditions reported by 40% or more of both groups include cancer,

Table 6.4

Key Findings From Participant Interviews Regarding Symptom Appraisal

Participant # (Age)	Cancer Type	Survivor Years	Cancer Experience	Insights	MCC
#1 (65–70) Off treatment	Solid tumor	20	Appraisal within the context of multiple years of cancer relapse and remission experience		13
#2 (71–80) On treatment	Solid tumor	5	Appraisal framed within the context of MCC and past symptoms and their impact on life	"You've got to just deal with it. You've got to adapt to it and keep moving."	10
#3 (65–70) Off treatment	Solid tumor	3	Appraisal based on total body awareness, age, medications, and other possible causes		11
#4 (70–80) Off treatment	Solid tumor	11	Appraisal based on cancer and chronic illness history, treatment history, acquired professional knowledge, public knowledge, age, medication, diet, and seeking out opinions of friends; uses an analytical and information-seeking approach		9
#5 (70–80) On treatment	Solid tumor	14	Appraisal based on self-awareness of body and knowing how to prevent symptom development related to cancer		8
#6 (65–70) Off treatment	Solid tumor	9	Appraisal focused on cancer and treatment first, then thinking about other possible causes		6
#7 (65–70) Off treatment	Solid tumor	6	Appraisal based on personal history with illness and family history with cancer and cardiac disease		8

Note. Survivor years indicate years of cancer survivorship since initial cancer diagnosis; MCC = multiple chronic conditions.

Table 6.5

Reported Chronic Illnesses or Conditions by Participant Group

Comorbidity	Active Treatment			Off Treatment			χ^2	*p*
	Rank	*n*	%	Rank	*n*	%		
Arthritis	1	19/32	59.4	1	21/29	72/4	1.49	.284
High blood pressure	2	18/32	56.3	5	15/30	50.0	.24	.622
Urine leaking	3	18/32	56.3	1	21/19	72.4	1.72	.189
Trouble remembering	4	16/32	50.0	2	19/30	63.3	1.12	.290
Gastroesophageal reflux disease	5	12/32	40.6	2	19/30	63.3	3.20	.074
Depression	6	11/32	34.4	9	10/30	33.3	.01	.931
Osteoporosis	7	10/32	31.3	3	17/29	58.6	4.62	.032
Overweight by 50 pounds or more	7	10/32	31.3	7	11/29	37.9	.30	.583
Problems with vision	7	10/32	31.3	4	12/29	54.5	.68	.411
Diabetes	8	9/32	28.1	16	5/30	16.7	1.16	.281
Bowel problem (nonconstipation)	9	8/32	25.0	13	7/30	23.3	.02	.878
Chronic lung disease	9	8/32	25.0	19	3/30	10.0	2.39	.122
Balance problems	10	7/32	21.9	8	11/30	36.7	1.64	.200
Prostate problems	10	7/32	21.9	22	1/30	3.3	4.74^	0.30
Thyroid problems	10	7/32	21.9	6	14/29	48.3	4.70	.030
Heart attack	11	6/32	18.8	20	2/30	6.7	2.01^	.156
Irregular heart beat	11	6/32	18.8	13	7/30	23.3	.20	.658
Two or more different cancers	11	6/32	18.8	10	9/29	31.0	1.24	.266
Problems with hearing	11	6/32	18/8	15	5/29	17.2	.02	.878
Knee or hip replacement	12	5/31	16.1	12	7/29	24.1	.60	.438
Other chronic illness	12	5/31	16.1	5	15/30	50.0	7.94	.005
Anemia	13	5/32	15.6	14	6/30	20.0	.20	.652
Asthma	13	5/32	15.6	11	8/30	26.7	1.14	.286
Confusing thoughts	13	5/32	15.6	16	5/30	16/7	.01^	.911

Table 6.5 (Continued)

Comorbidity	Active Treatment			Off Treatment			χ^2	*p*
	Rank	*n*	%	Rank	*n*	%		
Anxiety	14	4/32	12.5	12	7/30	24.1	1.39	.238
Heart operation	14	4/32	12.5	20	2/30	6.7	.60^	.438
Kidney problems	14	4/32	12.5	16	5/30	16.7	.22^	.642
Liver problems	14	4/32	12.5	20	2/30	6.7	.60^	.438
Blood clots	15	3/32	9.4	17	4/30	13.3	.24^	.623
Poor circulation	15	3/32	9.4	13	7/30	23.3	2.23^	.135
Heart failure	16	2/32	6.3	22	1/30	3.3	.29^	.593
Bleeding	16	2/32	6.3	18	3/29	10.3	.34^	.560
Shuffling/trembling	16	2/32	6.3	11	8/30	26.7	4.77^	.029
Broken bone	17	1/32	3.1	0	0/30	0	.95^	.329
Gall bladder problems	17	1/32	3.1	19	3/30	10.0	1.21^	.271
Many infections	17	1/32	3.1	21	1/29	3.4	.01^	.944
Stroke	17	1/32	3.1	20	2/30	6.7	.42^	.516
Ulcer	17	1/32	3.1	20	2/30	6.7	.42^	.516
Pancreas problems	0	0/32	0	22	1/30	3.3	1.08^	.298
Problems with ovaries or uterus	0	0/32	0	0	0/30	0	0.00^	0

Note. χ^2 = Pearson chi square; *df* = 1; ^ indicates one or more cells with expected count of less than 5.

Table 6.6

Reported Symptoms by Participant Group

Symptom	Active Treatment			Off Treatment			χ^2	*p*
	Rank	*n*	%	Rank	*n*	%		
Lack of energy	1	26/32	81.3	2	22/30	73.3	.56	.456
Pain	2	22/31	71.0	1	24/30	80.0	.67	.413
Feeling drowsy	3	20/31	64.5	3	19/30	63.3	.01	.923
Difficulty sleeping	4	17/31	54.8	6	16/30	53.3	.01	.906
Urinary symptoms	5	17/31	54.8	5	17/30	56.7	.02	.886
Feeling sad	6	15/31	48.4	9	11/30	36.7	.86	.355
Decreased sexual interest	7	13/30	43.3	14	6/30	20.0	.3.77	.052
Dry mouth	8	13/31	41.9	10	10/30	33.3	.48	.488
Numbness/tingling	8	13/31	41.9	8	13/30	43.3	.01	.912
Trouble remembering	8	13/31	41.9	4	18/30	60.0	1.99	.158
Skin changes	9	13/32	41.6	11	9/30	30.0	.76	.382
Itching	10	12/31	38.7	7	15/30	50.0	.79	.375
Feeling irritable	11	11/31	35.5	10	10/30	33.3	.03	.860
Nausea	11	11/31	35.5	15	4/30	13.3	4.03^	.045
Worried, anxious, nervous	12	10/31	32.3	5	17/30	56.7	3.68	.055
Short of breath	12	10/31	32.3	10	10/30	33.3	.01	.929
Feeling bloated	13	9/31	29.0	12	8/30	26.7	.04	.837
Diarrhea	14	8/31	25.8	14	6/30	20.0	.29	.590
Difficulty concentrating	14	8/31	25.8	10	10/30	33.3	.42	.519
Hot flashes	14	8/31	25.8	16	3/30	10.0	2.58^	.180
Dizziness	15	8/31	25.8	11	9/30	30.0	.13	.715
Cough	16	8/31	25.0	13	7/30	23.3	.02	.878
Lack of appetite	17	7/31	22.6	16	3/30	10.0	1.78^	.185
Taste changes	17	7/31	22.6	0	0/30	0	7.65^	.006

Table 6.6 (Continued)

Symptom	Active Treatment			Off Treatment			χ^2	*p*
	Rank	*n*	%	Rank	*n*	%		
"I don't look like myself"	18	6/31	19.4	0	0/30	0	6.44^	.011
Constipation	19	5/29	17.2	12	8/30	26.7	.76	.383
Mouth sores	20	4/31	12.9	16	3/30	10.0	.13^	.722
Sweating	20	4/31	12.9	14	6/30	20.0	.56^	.454
Unexpected weight loss	21	3/30	10.0	0	0/30	0	3.16^	.076
Difficulty swallowing	22	3/31	9.7	16	3/30	10.0	.01^	.966
Hair loss	23	2/30	6.7	16	3/30	10.0	.22^	.640
Vomiting	0	0/30	0	17	1/30	3.0	1.05^	.305

Note. χ^2 = Pearson chi square; *df* = 1; ^ indicates one or more cells with expected count of less than 5.

arthritis, hypertension, incontinence (leaking urine), trouble remembering, and gastroesophageal reflux disease. Several significant differences were found between groups regarding reported chronic illnesses. The off-treatment group reported significantly more osteoporosis, other chronic illnesses, thyroid problems, and shuffling and trembling than the active treatment group ($p < .05$). The active treatment group reported significantly more prostate problems than the off-treatment group; however, this is most likely due to underrepresentation of males in the off-treatment group.

The symptoms reported by 40% or more of both groups include lack of energy, pain, feeling drowsy, difficulty sleeping, urinary symptoms, numbness and tingling in hands and feet, and trouble remembering. The active-treatment group reported significantly more nausea, taste changes, and body image disturbance ($p<.05$) than the off-treatment group. Several group differences approached statistical significance. The active-treatment group also reported decreased sexual interest more than twice the rate of the off-treatment group ($p = .052$). The off-treatment group reported more worry, anxiety, and nervousness than the active-treatment group ($p = .055$).

Several items in the COSMOS v2 CoB may be classified as both chronic conditions and chronic symptoms, including problems with remembering, urinary symptoms, anxiety, and depression. Relationships between comorbidity burden and symptom perception scores for similar variables on the CoB and SxP were explored: trouble remembering; incontinence or general urinary symptoms; worry, anxiety, or nervousness; and depression or feeling sad or blue. Table 6.7 presents the data describing the relationships between these variables.

Table 6.7

Relationships Between Similar Items on the Comorbidity Burden Subscale and the Symptom Perception Subscale

Item	Pearson *r* (*p*)							
	1	2	3	4	5	6	7	8
1. Comorbidity burden subscale (CoB)[+] Trouble remembering	1.0	--	--	--	--	--	--	--
2. CoB[#] Anxiety or nervousness	.014 (.92)	1.0	--	--	--	--	--	--
3. CoB[#] Depression	.027 (.83)	.652* (.0001)	1.0	--	--	--	--	--
4. CoB Incontinence	.096 (.46)	-.106 (.42)	-.163 (.21)	1.0	--	--	--	--
5. Symptom perception subscale (SxP)^ Trouble remembering	.638* (.0001)	.126 (.33)	.09 (.49)	.038 (.77)	1.0	--	--	--
6. SxP^ Worried, anxious, nervous	-.137 (.29)	-.026 (.84)	-.064 (.62)	.051 (.70)	.037 (.77)	1.0	--	--
7. SxP^ Feeling sad or blue	-.108 (.40)	-.033 (.80)	-.054 (.68)	.058 (.66)	.055 (.67)	.997* (.0001)	1.0	--
8. SxP^ Urinary problems (going often, pain, leaking)	-.119 (.36)	-.08 (.54)	-.109 (.40)	.115 (.38)	.038 (.77)	.993* (.0001)	.994* (.0001)	1.0

Note. + denotes assessment time frame of over the past year; # denotes assessment time frame of lifetime; ^ denotes assessment time frame of "over past month"; * indicates significance.

Symptom Attribution

The symptom attribution checklist included five possible options for each symptom with more than 30 different combinations. Most participants chose multiple responses that reflected their unique symptom perceptions.

Symptom attributions were grouped into three distinct categories for analysis. Aging-related attribution included the following participant selections: aging, aging and cancer, aging and noncancer medications, aging and other causes, and any other combinations that included aging. The cancer and cancer treatment attribution category included all combinations with cancer and cancer-related treatments except those that included aging. The other category included noncancer medications and other attributions. Table 6.8 includes the attribution results for the most frequently reported symptoms.

Table 6.9 includes specific attributes identified in the “other” category. The data listed in the other category for symptom attribution can be grouped into several broad categories, including acute or chronic illness or conditions, acute or chronic physical or psychological symptoms, behavior-related causes, or life activities.

Significant differences between groups regarding symptom attribution were seen in only 6 out of 32 symptoms reported (lack of energy, feeling drowsy, feeling worried/anxious/nervous, taste changes, lack of appetite, and nausea). Those off treatment who reported lack of energy and feeling drowsy reported no cancer-related attribution as compared to the active-treatment group. Those on active treatment reported significantly more anxiety attributed to cancer-related issues as compared to off-treatment participants. Participants on active treatment reported significantly more attribution to

Table 6.8

Attributions for Most Frequently Reported Symptoms by >40% of the Study Sample

Symptom and Attribution^	Active Treatment (*N* = 32) *n* (%)	Off Treatment (*N* = 30) *n* (%)	χ^2 (*p*)
Lack of energy			17.25 (.002)
Age-related	12/26 (46.2)	13/22 (59.1)	
Cancer-/treatment-related	12/26 (46.2)	0/22 (00.0)	
Other	2/26 (7.7)	9/22 (40.9)	
Pain			6.44 (.169)
Age-related	14/21 (66.7)	9/25 (36.0)	
Cancer-/treatment-related	3/21 (14.3)	4/25 (16.0)	
Other	4/21 (19.0)	12/25 (48.0)	
Feeling drowsy			12.61 (.013)
Age-related	8/19 (42.1)	12/19 (63.2)	
Cancer-/treatment-related	9/19 (47.4)	0/19 (0.0)	
Other	2/19 (10.5)	7/19 (36.8)	
Difficulty sleeping			6.36 (.174)
Age-related	3/17 (17.6)	9/16 (56.3)	
Cancer-/treatment-related	5/17 (52.9)	1/16 (5.9)	
Other	9/17 (29.4)	6/16 (35.3)	
Urinary symptoms			8.22 (.084)
Age-related	6/17 (35.5)	13/16 (81.3)	
Cancer-/treatment-related	8/17 (47.1)	1/16 (6.3)	
Other	3/17 (17.6)	2/16 (12.5)	
Feeling sad			4.57 (.334)
Age-related	4/14 (14.3)	4/10 (40.0)	
Cancer-/treatment-related	6/14 (42.9)	1/10 (10.0)	
Other	6/14 (42.9)	5/10 (50.0)	
Decreased sexual interest			6.86 (.143)
Age-related	8/13 (61.5)	4/6 (66.7)	
Cancer-/treatment-related	3/13 (23.1)	0/6 (0.0)	
Other	2/13 (15.4)	2/6 (33.3)	
Dry mouth			4.37 (.358)
Age-related	2/13 (15.4)	1/10 (10.0)	
Cancer-/treatment-related	3/13 (23.1)	1/10 (10.0)	
Other	8/13 (61.5)	8/10 (80.0)	
Numbness and tingling			2.24 (.691)
Age-related	2/8 (25.0)	2/12 (16.7)	
Cancer-/treatment-related	1/8 (12.5)	3/12 (25.0)	
Other	5/8 (65.5)	4/12 (58.3)	
Trouble remembering			3.52 (.474)

Table 6.8 (Continued)

Symptom and Attribution^	Active Treatment (*N* = 32) *n* (%)	Off Treatment (*N* = 30) *n* (%)	$\chi 2$ (*p*)
Trouble remembering (continued)			
Age-related	11/13 (86.6)	13/18 (72.2)	
Cancer-/treatment-related	0/13 (0.0)	1/18 (5.6)	
Other	2/13 (15.4)	4/18 (22.2)	
Worried, anxious, nervous			11.27 (.024)
Age-related	2/10 (20.0)	5/17 (29.4)	
Cancer-/treatment-related	4/10 (40.0)	1/17 (5.9)	
Other	4/10 (40.0)	11/17 (64.7)	
Itching			2.67 (.613)
Age-related	2/12 (16.7)	3/15 (33.3)	
Cancer-/treatment-related	3/12 (25.0)	1/15 (6.7)	
Other	7/12 (58.3)	11/15 (73.3)	

Note. The percent sign (%) denotes the number of participants reporting a specific attribution divided by the total number reporting the symptom; χ^2 = Pearson chi square; *df* = 4, ^ indicates one or more cells with expected count of less than 5.

Table 6.9

Other Attributions for Selected Frequently Reported Symptoms

Symptom	Descriptions for "Other" Attributions
Pain	Tendonitis, fibromyalgia, shingles, "overdoing," foot problems, arthritis, spinal stenosis, surgery, neuropathy, "pulled muscles," degenerative disc disease, migraines
Lack of energy	Multiple sclerosis, fibromyalgia, shingles, pain, chronic pain, lack of sleep, stress, depression, chemical sensitivities, overweight, "not slowing down," congestive heart failure, body rashes, amyotrophic lateral sclerosis (ALS), travel, arthritis
Feeling drowsy	Noncancer medications, shingles, "too many activities," "not sleeping well at night," stress, caring for wife, chemical sensitivities, fatigue, ALS, lack of exercise, physical exhaustion
Trouble remembering	Multiple sclerosis, fibromyalgia, stress, noncancer medications
Worried, anxious, nervous	Treatments, doctor's appointments, family members, stress, work, "life in general," a busy schedule, ill spouse, neuropathy, caregiver, "husband not working," cardiac issues, relationships, depression
Urinary symptoms	Chronic pelvic prolapse, childbirth, prostate issues, noncancer medications, overactive bladder, recurrent urinary tract infections, hysterectomy
Difficulty sleeping	Napping in afternoon, husband snoring, shingles, anxiety, pain, lack of exercise, stress, caregiver, trouble falling asleep, frequent urination, sleep apnea, upset stomach, acid reflux, feeling overwhelmed, exhaustion, caffeine, depression, low estrogen
Itching	Noncancer medicines, shingles, Arizona weather, dry skin, allergies, leg ulcer, body rash, eczema

cancer and cancer treatment for nausea, lack of appetite, and taste changes than off-treatment participants (p = .045, p = .01, and p =.036, respectively).

Relationship of Comorbidity Burden, Symptom Perception, and General Functioning

Differences between groups regarding comorbidity burden, symptom perception, and general functioning were explored. Table 6.10 includes specific data on comorbidity, comorbidity burden, symptom burden, and function as measured in this study. Active-treatment and off-treatment groups were comparable with regard to reported medications, comorbidity burden, number of symptoms, symptom burden, and functional performance and current activity; however, off-treatment participants reported significantly more chronic illnesses than those on active treatment.

The relationship between variables of CoB, SxP, and functional performance was explored. Table 6.11 displays the correlations between key exploratory variables. A moderate correlation was found between CoB and SxP (r = .460, p = .0001). In addition, the functional interference score had a moderate, significant correlation with the CoB score (r = .296, p = .021) and the SxP score (r = .423, p = .001). The number of medications was not found to be significantly correlated with either CoB (r = .217, p>.05) or SxP (r = .162, p>.05).

Reliability

Test-retest reliability was analyzed using an ICC to determine the repeatability and stability of the scale results on a minimal subset of the off-treatment study sample (n = 15). The CoB was excellent (ICC = .917), while the stability of the SxP stability was acceptable (ICC = .696).

Table 6.10

Descriptive Data for Comorbidity, Symptoms, and Physical Function

Descriptive Data	Active Treatment *M* (*SD*)	Off Treatment *M* (*SD*)	Statistic (*df*)	*p*
Number of medications reported	9 (3.94)	8 (4.25)	t = .98 (58)	.333
Number of chronic illnesses reported	7.9 (2.99)	9.9 (3.4)	t = -2.48 (60)	.016
Range	2–14	3–19		
Comorbidity burden score	17.1 (8.47)	21.0 (8.14)	t = -1.83 (60)	.072
Range	2–44	1–35		
Number of symptoms reported	10.31 (4.8)	9.8 (4.78)	t = .42 (60)	.676
Range	1–22	1–23		
Symptom burden score	18.9 (9.89)	16.7 (7.57)	t = .66 (60)	.511
Range	2–44	1–35		
Functional performance score	13.2 (5.9)	11.4 (4.5)	t = 1.29 (59)	.201
Range	5–28	5–20		
Activity now score			χ^2 = 4.8 (4)	.395
Normal	12.9%	10.0%		
Some symptoms, no extra rest	45.2%	33.0%		
Some additional rest (less than half day; more than half day; unable to get out of bed)	40.3%	56.7%		

Table 6.11

Correlations of Key Exploratory Variables (Pearson's r *Statistic)*

Key Variable	CoB Score	Medication #	SxP Score	FIS Score
CoB score	1.00	.217 (p = .096)	.460 (p = .0001)	.296 (p = .021)
Medication #	--	1.00	.162 (p = .217)	.240 (p = .067)
SxP score	--	--	1.00	.423 (p = .001)
FIS score	--	--	--	1.00

Note. CoB = comorbidity burden subscale; SxP = symptom perception subscale; FIS = functional interference scale.

Feasibility

Based on the pilot data, it is feasible to collect critical patient-centered data on comorbidities and symptoms through self-report. There were no identifiable patterns found for missing data; however, participants with missing data may have lower comorbidity burden and symptom perception scores. Missing data issues may be mitigated with a formatting revision of each subscale. Electronic versions of each subscale may be constructed to build in guides for scale completion with required fields; however, this method of delivery may not be feasible for all older adults.

Discussion

Two out of 62 participants required assistance in completing the COSMOS v2; both participants appeared to be physically frail. The feasibility of COSMOS completion by frail or fatigued older adults may be affected by the length of the subscales, which may increase survey burden. Although the average completion time for each COSMOS v2 subscale was reasonable, at 9 minutes for the CoB and 11.5 minutes for SxP, the range for completion of both subscales approached 50 minutes or longer for some participants. This could impair clinical utility unless it was used as part of a patient portal that was completed online prior to clinic appointments.

Construct Validity

Cancer survivors off treatment reported a significantly higher number of comorbidities than the active-treatment group, including osteoporosis, thyroid problems, and shuffling and trembling. Although the total CoB scores were higher in the off-treatment group, the difference was not statistically significant ($p>.05$). There was a high

degree of variability on this measure, and the smaller sample size may have limited power to detect significant differences. In addition, participant interviews indicate that personal experience with cancer and chronic illness is integral to symptom appraisal. However, participant interview data should be cautiously interpreted, because it represents cancer survivors of 3 to 20 years and mostly off treatment.

Current cancer survivorship literature suggests that older long-term cancer survivors may have a greater number of comorbidities than before the diagnosis (Kenzik, Kent, Martin, Bhatia, & Pisu, 2016; Leach et al., 2015); however, Grov, Fossa, and Dahl (2011) found no differences in reported comorbidities between older cancer survivors (≥70 years) compared to noncancer controls. Older cancer survivors may experience chronic conditions due to direct or indirect long-term effects of cancer therapies in conjunction with existing comorbidities prior to diagnosis and treatment of new conditions due to the aging process. Further longitudinal study is needed regarding the development of posttherapy chronic conditions in the context of physiologic aging. Additionally, once cancer survivors have finished initial treatment, they may shift their focus to the diagnosis of other chronic conditions and management of previous conditions.

These findings may indicate that cancer-related treatment does not have a direct impact on comorbidity burden or that chronic conditions are well managed and have a minimal impact on overall burden. Individuals have unique expectations of aging within their personal view of health and well-being that provides the foundation for perception of comorbidity burden. In addition, overall comorbidity burden scores may indicate adaptation and adequate self-management of comorbidities that effect daily life and the

perceived quality of life of older adults. It has been suggested that chronic illness experiences may protect individuals from the impact of a cancer diagnosis (Blank & Bellizzi, 2008).

The SxP detected minor differences between participants on active treatment as compared to those off treatment. Three items that were reported significantly more in the active-treatment group were nausea, taste changes, and "I don't look like myself"; nausea was reported almost three times more in the active-treatment group. Seven active-treatment participants reported taste changes, and "I don't look like myself" was reported by 6 active-treatment participants, but no off-treatment participants reported either of these symptoms. These symptoms are expected in cancer survivors undergoing active treatment and support construct validity of the SxP. Of interest, significant differences in symptom attribution were noted between the active-treatment and off-treatment groups in almost 19% of the symptoms measured.

The "lack of energy" and "feeling drowsy" items demonstrated a clear pattern of attribution, with the active-treatment group attributing these symptoms to aging and cancer-related causes while the off-treatment group attributed the symptoms to aging and other causes. Anxiety was attributed more to aging and other causes in the off-treatment group compared to cancer-related and other causes in the active-treatment group. The active-treatment group attributed symptoms of nausea, taste changes, and lack of appetite mostly to cancer and cancer treatments compared to the off-treatment group. These nuances suggest that the SxP and symptom-attribution descriptors have potential to discriminate between known groups, and thus support validity of the symptom perception construct.

The analysis for the symptom attribution list revealed three clinically meaningful categories, including aging-related, cancer-related, and other. The other category for symptom attribution included a wide variety of chronic conditions, symptoms, and life challenges. Life challenges noted by participants included relationships, life events, and health- and wellness-related issues. Using these categories illuminates specific differences and similarities between on-treatment and off-treatment older cancer survivors with regard to reported symptoms. The difference between groups regarding symptom attribution reflects the unique perspective of cancer survivors along the treatment trajectory. Both groups primarily attributed trouble remembering to aging; however, it is well documented that cancer treatments may have a residual effect on functional memory (Mandleblatt, Jacobsen, & Ahles, 2014).

It has been suggested that the traditional retirement age may be a developmental marker for changes in perception of discomfort, from abnormal to a normal expectation that comes with age (Williamson & Schulz, 1995). The distinction among the disease process, treatment side effects, and the normal physiological changes of aging may guide individual health-behavior choices. Prohaska, Keller, Leventhal, and Leventhal (1987) revealed that mild symptoms of short or long duration are more likely to be attributed to aging than severe, short-term symptoms. In addition, cancer-related symptoms may be perceived as a normal part of aging or as being caused by other health problems (Repetto et al., 1998). The COSMOS v2 pilot results suggest a possible shift in attribution of specific symptoms in cancer survivors from active treatment to off treatment. Cancer survivors may also shift their contextual focus for symptom attribution from cancer and treatment to a more global perspective of chronic illness history inclusive of cancer.

Several items on the CoB and SxP can be considered as both chronic conditions and symptoms, including trouble remembering, anxiety, depression, and urinary symptoms/incontinence. Depression and anxiety were strongly associated within their respective subscales; however, there was not a significant relationship between these items across subscales. This result suggests that each subscale measured the item differently based on the time frame reference and the participant's perception of anxiety and depression as a symptom or chronic condition. The urinary symptoms and incontinence items were not related across the two subscales, indicating that each item measured a different dimension of urinary issues. The "trouble remembering" items on both subscales were significantly related, indicating a potential measurement overlap of this item. These results suggest that assessment time frame is an important dimension of measurement of chronic conditions and symptoms, and may affect overall construct validity.

Exploratory Relationships Between Key Variables

The relationship between key variables of comorbidity burden, symptom perception, and functional interference was explored. In this study population, a moderate relationship was found between CoB and functional interference scores, suggesting that increased comorbidity burden is related to increased interference with general functioning. Symptom perception scores had a moderate relationship with functional interference scores, suggesting that increased symptom perception is related to increased functional interference. Finally, the strongest relationship was found between CoB and SxP scores. This finding implies that increased comorbidity burden is significantly related to increased symptom perception. These results suggest that there is a critical

relationship between comorbidity burden, symptom perception, and functional interference, and further support validity of COSMOS v2 as a sensitive measure in older cancer survivors. Furthermore, these relationships are supported by reported research focused on older adult cancer survivors with comorbidities and symptoms (Lacasse, 2016b). A more refined measure of CoB may illuminate this relationship further. In addition, a deeper understanding of the role of symptom attribution, perceptions of quality of life, and expectations of aging may add to the knowledge and understanding of this relationship.

Reliability

The CoB scores were relatively low for those with multiple chronic illnesses, which may indicate that only the "active" chronic illnesses that are associated with symptoms are acknowledged as having an impact on daily life. Older adults may also tolerate and minimize "bother" as part of their perception of symptoms of aging. The high test-retest reliability of the CoB is an expected outcome of the measurement of self-reported comorbidity as a stable construct over time (Katz et al., 1996). This supports construct validity by demonstrating the stability of the measure of comorbidity burden over time in the research sample.

The SxP scores were slightly higher in the active- treatment group; however, there was not a significant difference between groups. The test-retest reliability of the SxP was acceptable based on the expected variability of symptoms over time in the context of multiple chronic illnesses. Furthermore, the test-retest reliability in this study is comparable to other symptom-assessment tools used in oncology populations (Chang, Hwang, Feuerman, Kasimis, & Thaler, 2000; Stapleton, Holden, Epstein, & Wilkie,

2015). These results support the stability of the SxP measure over time in a construct that has potential to have patient-specific variability across the trajectory of cancer survivorship.

Subscale Revisions

Based on the descriptive item analysis and item-to-item correlations in the CoB, the following items should be revised to increase the parsimony of the subscale and decrease instrument burden:

- The items addressing heart attack burden and heart operation for vessel or valve disease burden scores were highly correlated (r = .901, p = .0001), indicating significant overlap of items. These items were collapsed into one cardiac-related item.
- The items addressing select gastrointestinal conditions related to pancreas and liver were collapsed into one item due to minimal reporting (less than 5%) for each of these conditions. Gastrointestinal reflux disease, gall bladder disease, and ulcers were retained as separate conditions based on age-related risk factors for developing these chronic conditions (Tabloski, 2014).
- Asthma and COPD had a moderate relationship (r = .306, p = .016) and were collapsed into one item due to the similarity in symptoms and overlapping disease processes.
- The item "broken bones" was reported by <5% of participants and was clustered with osteoporosis and bone loss as indicators of bone health (Tabloski, 2014).
- The item "multiple infections" was deleted due to minimal reporting (less than 5%), although it may be relevant in a sample of survivors of hematologic malignancies.
- The item labeled "bleeding" was not frequently chosen (less than 10%); however, this item was retained and expanded to "bruising or bleeding," since this may occur with older individuals on cancer treatment, which affects bone marrow, or those off treatment who have cardiovascular disease and are treated with anticoagulant therapy.
- The prostate-specific item was revised and incorporated into a more global item addressing genitourinary problems, either male or female. This revision simplifies the subscale to be gender neutral.

Both the CoB and SxP incorporate the overall unique patient experience with chronic illness and symptoms. The COSMOS v2 subscales include four chronic conditions (trouble remembering, incontinence or urinary symptoms, anxiety, and depression or feeling sad) that are commonly found in older populations and are also classified as symptoms. Only one of these chronic conditions, trouble remembering, was moderately correlated with the corresponding symptom. These items were retained in both subscales because trouble remembering, urinary symptoms, anxiety, and depression, may be chronic conditions, acute indicators of a change in health, or effects of cancer and cancer treatments in cancer survivors (Hewitt et al., 2006; Tabloski, 2014). The revised CoB includes 33 items, as listed in Table 6.12.

The list of items in the SxP parallels the list of symptoms in the Memorial Symptom Assessment Scale (Chang, Hwang, Feuerman, Kasimis, et al., 2000). This list includes the recommended set of core symptoms for adult patient-reported outcomes (Reeve et al., 2014), core symptoms included in the Symptom Distress Scale (Stapleton et al., 2015), and select symptoms from the recommended set of core symptoms for patient-reported outcomes—focused on prostate, ovarian, and head and neck cancers (Chen et al., 2014; Chera et al., 2014; Donovan et al., 2014). Each of the 32 symptoms on the SxP was selected by at least 3 participants, with the exception of vomiting. Based on the global nature of the SxP, it is recommended that the list of symptoms remain intact.

Within the past 5 years, the PROMIS (Patient-Reported Outcomes Measurement Information System) tools have been developed and widely tested as standard person-centered measures for multiple dimensions of physical, mental, and emotional health for adults and children (www.healthmeasures.net/explore-measurement-systems/promis).

Table 6.12

Revised Comorbidity Burden Subscale Items

Items Retained	Items Revised/Deleted
• Heart failure • Hypertension • Arrhythmias • Clots • Poor circulation • Stroke • Shuffling/tremors • Gastrointestinal reflux disease • Peptic ulcer disease • Gall bladder disease • Bowel function alterations • Diabetes • Obesity • Kidney problems • Balance problems • Joint replacement • Arthritis • Thyroid problems • Anemia • Hearing problems • Vision problems • Urinary incontinence* • Confused thoughts • Depression* • Anxiety* • Trouble remembering*	<u>Revised Items</u> • Heart disease (heart attack and heart operation) • Chronic lung condition (asthma and chronic obstructive pulmonary disease • Gastrointestinal conditions (liver disease and nondiabetic pancreatic disease) • Bruising or bleeding • Genitourinary problems (if male, prostate problems; if female, ovary and uterus problems) • Bone health (osteoporosis/bone loss/broken bones) <u>Deleted Items</u> • Multiple infections

Note. * = chronic conditions that overlap with acute and chronic symptoms.

Each COSMOS subscale might yield more clinically useful information if the bother/ interference scale for each comorbidity and symptom was expanded to match the five-point Likert scale used in the PROMIS tools. This scale ranges from “not at all” to “very much” (www.nihpromis.org/measures/SampleQuestions#fatigue).

Figure 6.1 is an example of a revised item in the comorbidity subscale. Figure 6.2 is an example of a revised item on the symptom-perception subscale that incorporates changes to facilitate a clearer visual format and future translation to an online version. The current revision of the instrument, COSMOS v3, is in Appendix J.

Limitations

A sample of 62 participants with 30 participants per group can be considered a minimal number for initial health-care-related instrument development focused on feasibility and initial psychometric testing (Hertzog, 2008; Johanson & Brooks, 2010; Julius, 2005). Recommendations for comprehensive instrument development beyond the pilot phase requires a large sample size ranging from 10–15 participants per item for initial instrument testing (Pett, Lackey, & Sullivan , 2003) to 300 participants or more for complex multidimensional constructs (Netemeyer, Bearden, & Sharma, 2003; Nunally,

Have you ever been told by a health care provider that you have arthritis? _____No _____Yes **If you answered yes**, → please answer the question on the right.	How much does this health problem affect your current daily life? (Check **one**.) ☐ Not at all ☐ A little ☐ Somewhat ☐ Quite a bit ☐ Very much

6.1 Example of revised comorbidity burden subscale item: Arthritis.

During the past week, have you had fatigue or lack of energy? _____No **If you answered no**, please go to Question 5. _____Yes **If you answered yes**, please answer the questions in the next 2 columns →	4b. **How much does this symptom bother you?** [Please check one.] ☐ Not at all ☐ A little bit ☐ Somewhat ☐ Quite a bit ☐ Very much	4c. **If you answered yes to the question about the symptom**, please answer the following question. Check **one** of the following statements that you think is true about your symptom of fatigue. ☐ The cause of this symptom is **mostly** age-related. ☐ The cause of this symptom is **mostly** related to my cancer and/or cancer treatments. ☐ The cause of this symptom is **mostly** related to a noncancer condition or treatment. ☐ This symptom has some other cause. (Write in what you think is causing the symptom.)

Figure 6.2 Example of revised symptom burden subscale item: Fatigue.

1994). Although this study sample is small, the study yielded valuable information for further revision and psychometric testing of COSMOS.

The sample studied in this pilot included a diverse group of cancer diagnoses and does not fully represent the four most common cancers diagnosed in adults, including cancers of the lung and bronchus, prostate (men), breast (women), and colon and rectum (Miller et al., 2016). The active-therapy group does not fully represent the typical range of cancer-related treatments, such as chemotherapy and radiation therapy, that may affect the symptoms reported by this sample. In addition, the study sample does not equally represent gender in the active- and off-treatment groups. This imbalance of gender representation was likely due to specific recruitment patterns and may lead to missed opportunities for discovery of gender-specific symptom and symptom-attribution reporting patterns. This study provides general information about older cancer survivors living with multiple chronic illnesses and symptoms and important information for revisions of the COSMOS v2.

The assessment timeframe for comorbidities and symptoms in the COSMOS v2 ranges from history across an individual's lifespan through the previous month. The CoB includes two specific time frames for participants to consider regarding their history with chronic conditions. Questions within the CoB are clustered by time frame, including if the participant has ever been diagnosed with a specific illness, or specific chronic conditions diagnosed or experienced within the previous year. The SxP is focused on symptom recall over the previous month. This variation in the time period of recall may potentially influence the individual's accuracy of self-reporting chronic illnesses and symptoms. In addition, trouble remembering was reported by ≥50% of participants, and

this may influence the accuracy of self-report when asked to recall chronic conditions or symptoms over an extended period. The CoB demonstrated temporal stability, indicating general reliability of reporting comorbidity history. Based on the focused interview data, the SxP scale may not reflect an accurate symptom recall over a 1-month time period. One recommendation for measuring symptoms is to change the symptom recall interval to 1 week; this time frame would focus on the reporting of the most current and bothersome symptoms and potentially increase accuracy of symptom reporting.

Twenty-four percent of the cancer survivor population screened for this study met the comorbidity eligibility criteria of having two or more chronic illnesses or conditions in addition to cancer, which is lower than the reported 33.2% in the general population over 65 years (Ward, Schiller, & Goodman, 2014). Several cancer survivors who met eligibility criteria declined participation due to time restriction, fatigue/weakness from treatment, discomfort with answering the screening questions, or cancer recurrence.

During the study recruitment period, which extended over several years, general cancer treatment practices remained stable; however, the treatments themselves evolved to include newer approaches, including targeted therapies (Hewitt et al., 2006; IOM, 2013). The variables most likely to show the impact of the time frame for recruitment are the treatment type and associated treatment-related symptoms. All study participants had a history of multiple types of cancer therapies, which adds to the homogeneity of the study population.

Multiple statistical tests were used to analyze data collected for each subscale, functional interference scale, and demographic. This pilot study yielded important information about the performance of the COSMOS v2 that should be interpreted with

caution based on the sample size and the risk of Type 1 error. Each significant statistic was carefully reviewed and considered using a conservative interpretation of results. Decisions for scale revisions were based on study results and validation by relevant cancer survivorship literature.

Implications for Practice and Research

The COSMOS v2 shows promise as a reliable patient-centered measure for comorbidity burden and symptom perception in older adult cancer survivors. Further testing of diagnosis-specific cancer survivor groups, including breast, prostate, lung, and colon cancer survivors, treatment-specific groups, and specific cohorts of older adults (such as 60–74 years compared with those 75+ years), is needed to further expand the instrumentation data. In addition, differences between cancer survivors receiving radiation therapy, chemotherapy, and hormonal therapy may emerge in the symptom perception and attribution data.

The Charlson Self-Report Comorbidity Index can be used to further validate the construct of comorbidity burden as measured by the CoB (Katz et al., 1996). One recommendation is to use established measures to validate findings, including the Expectations of Aging Survey, which incorporates the dimensions of physical and mental health and cognitive functioning (Sarkisian, Steers, Hays, & Magione, 2005). In addition, an established measure of general function, such as the Medical Outcomes Study Survey: 12-item Short Form instrument, or the PROMIS measure for physical function, can be used to assist in establishing criteria validity of this new measure (Hamoen, DeRooij, Witjes, Barentsz, & Rovers, 2015; Jensen et al., 2015). The COSMOS may also be useful in clinical research that focuses on the impact of comorbidity burden and symptom

burden in older adults with multiple chronic illnesses. In addition, this scale may be used to measure of the effect of patient-centered and population-specific interventions aimed at minimizing both comorbidity and symptom burden.

This instrument has the potential to yield clinically meaningful data to facilitate collaboration between cancer survivors and health care providers regarding coordination of care and symptom management. The COSMOS may be a useful tool to integrate into a geriatric assessment and assist in screening for both comorbidity and symptom burden that has a direct impact on individual quality of life. Clinicians may be able to use the CoB and SxP as a basis for initial collaboration with patients in building a dynamic information map in the electronic record to chart individual comorbidity and symptom pathways for clinical and self-management strategies. Information from the CoB and SxP also has the potential to be useful in measuring clinical care outcomes and planning survivorship care transitions.

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CHAPTER 7

CONCLUSIONS AND RECOMMENDATIONS

Study Summary

Cancer survivors age 65 years and older are a rapidly growing population that has unique needs with regard to the integration of the health care specialties of geriatrics and oncology, guidelines for cancer survivor care, chronic illness management, and innovative approaches to supporting quality of life. More than 60% of all cancers are diagnosed in individuals aged 60 years or older, and 50% or more of this population experiences chronic conditions and symptoms (Deckx et al., 2012; Miller et al., 2016). Multiple chronic illnesses and their associated symptoms often play an important role in the early detection and successful treatment of common cancers experienced by older adults (Wildiers et al., 2014). In addition, older adults with cancer and two or more comorbidities have an increased frequency of geriatric syndromes that adds a degree of complexity to the measurement of comorbidity burden and symptom perception (Vetrano, et al., 2016).

The care needs of the gero-oncology survivorship group often include careful management of chronic and late effects of cancer and its treatment, complex comorbidities, health care team collaboration across the care spectrum, and care coordination and transition management (Parry, Kent, Mariotto, Alfano, & Rowland,

2011). This group of cancer survivors may benefit from a standardized approach to care transitions from diagnosis and treatment phase (early survivorship) through the ongoing survivorship phase, which incorporates important aspects of a patient-centered, gero-centric cancer survivorship care plan.

The cancer survivorship population is primarily comprised of older adults, with 74% being age 60 and older and almost 47% of survivors being age 70 or older (Miller et al., 2016). The most prevalent cancer diagnoses in men include prostate, colon and rectum, melanoma, and urinary bladder cancers, and the most prevalent cancer diagnoses for women include breast, uterine, colon and rectum, thyroid, and melanoma (Miller et al., 2016). Each of these cancers has a unique diagnosis and treatment trajectory with associated short- and long-term health effects. Acute effects of cancer treatment are often related to the specific therapies being received; however, symptoms may persist long after treatment is finished and may blend with similar symptoms from coexisting chronic conditions (Miller et al., 2016; Parry et al., 2011).

A review of the relevant literature exploring the relationship between chronic illness and the symptom experience in older adults with cancer revealed that on average, older adult cancer survivors have two to four chronic conditions in addition to cancer (Lacasse, 2016b). Furthermore, the number of chronic conditions varies based on age, the specific cancer diagnosed, and treatments received. In addition, older adult cancer survivors were found to have a wide range of reported symptoms, which varied based on whether survivors were on active treatment or off treatment and whether or not they had comorbidities. Only ~~two~~ three studies addressed symptom attribution that included the survivor's perception of the cause of specifically identified symptoms (Heidrich, Egan,

Hengudomsub, & Randolph, 2006; Royer, Phelan, & Heidrich, 2009; Spoelstra et al., 2015).

The literature review revealed several challenges in comorbidity and symptom measurement (Lacasse, 2016b). The basis of these challenges resides in the wide variety of comorbidity and symptom measurement tools. A review of the comorbidity measures currently used in cancer care revealed a focus on the medical, physiologic perspective of comorbidity as a predictor of risk of mortality and gauge for recommending appropriate treatment options. Although this approach to comorbidity measurement has utility in treatment of acute and chronic conditions, these measures do not include a quality-of-life perspective. Examination of the impact of each comorbidity on life functioning allows for a patient-centered approach to measuring general comorbidity burden. A review of the symptom measures used in cancer survivorship research revealed a general list of core symptoms with a wide variety of other symptoms. Symptom measures used in cancer survivorship appear to be tailored to specific study aims or study populations.

Several studies in the review explored the relationship between comorbidity, symptoms, and functioning in older adults with cancer (Lacasse, 2016b). Nine out of 13 studies reviewed reported that increased symptoms and increased comorbidities had a negative impact on physical functioning. This information illuminated the need to continue to monitor these critical variables throughout the cancer survivorship trajectory in conjunction with normal aging changes, newly emerging comorbidities, and symptoms. Close monitoring of critical aspects of aging and cancer survivorship may provide important information for health care providers to use when planning and adjusting long-term survivorship care plans.

Study Aims and Significance

The broad goal of this study was to assess the validity of a self-report tool for measuring comorbidity burden and symptom perception that can be easily used in the clinical setting as an integral component of the comprehensive geriatric assessment of older adults with cancer. The purpose of this methodological study was to conduct initial psychometric testing of the Comorbidity and Symptom Measurement in Oncology Scale (COSMOS) and examine the feasibility of utilizing it with older adults with cancer and comorbidities. The following were the specific aims:

Aim 1.0: Determine the content validity of the COSMOS by utilizing a survey method that includes both quantitative and qualitative data collection from a panel of expert clinicians/researchers in oncology, gerontology, and geriatric oncology and symptom assessment and management.

Aim 2.0: Determine the construct validity of the COSMOS by utilizing a mixed-method approach with known groups of older adults on active cancer treatment and off treatment.

Aim 3.0: Determine the initial test-retest reliability of the COSMOS in a group of older adult cancer survivors who have finished active cancer treatment.

Aim 4.0: Determine the feasibility of a self-administered measurement tool of comorbidities and symptoms in a population of older adults with cancer, including tool completion time, response patterns, tool comprehension, missing items, and patterns in missing data.

Secondary Aim: Explore the relationship of comorbidities, symptoms, and general functioning.

Scale Development and Content Validity

The COSMOS uniquely combines a self-report assessment of a broad range of chronic illnesses and conditions commonly found in older adults, such as cardiovascular, arthritis, renal, gastrointestinal, hepatic, endocrine, and neurological disease processes (Carlson, Merel, & Yukawa, 2015; Tabloski, 2014) with a comprehensive symptom-

perception assessment. The COSMOS is based on a blended conceptual model incorporating key elements from the Theory of Unpleasant Symptoms (Lenz, Pugh, Milligan, Gift, & Suppe, 1997) and the Common Sense Model of symptom perception and appraisal (Leventhal, Meyer, & Nerenz, 1980). This blended model describes physiological, psychological, and situational factors that have an integrated effect on symptom perception and the cognitive and emotional representation of illness. These factors may moderate the perception of symptoms that has an impact on the outcomes of the overall symptom experience and comorbidity management.

Comorbidity burden was defined as the presence of disease and its impact on the daily life of the patient. Symptom perception was defined as the presence of the symptom and the impact of the symptom on daily life. The concept of symptom perception also includes elements of symptom distress as it relates to the individual survivor. Symptom attribution was also measured as a descriptor of a survivor's perception of the cause of each symptom that was reported. The combined data from the COSMOS have the potential to inform health care providers across the cancer survivor care continuum about the survivor's perspective in the evaluation of critical components of their survivorship care, such as chronic illness and symptoms.

Content validity for COSMOS version 1 (v1) was derived from a critical evaluation of relevant literature and review by a panel of experts. The scale revisions included the addition of three items, deletion of three items, and modification of four items. The content validity index for the comorbidity burden subscale was .80 (p = .05), and .98 (p = .05) for the symptom perception subscale. Results from the initial evaluation of content validity were incorporated into the revised scale, COSMOS v2.

The next step in the instrument development process was to field test the instrument in a representative population sample (Polit & Beck, 2017). In this case, an appropriate field test of COSMOS v2 included quantitative assessment of the measure's performance in a sample of older cancer survivors with multiple chronic illnesses and symptoms. The ability of COSMOS v2 to detect differences in known groups of survivors either on active treatment of off treatment was also measured.

Description of Instrument

The comorbidity burden subscale (CoB) is comprised of a list of yes/no questions to assess the presence of comorbidity and a scale measuring the effect of each comorbidity on daily life. The CoB score includes 38 chronic illnesses and conditions and is calculated by adding the comorbidity-presence and effect-of-comorbidity scores. Total scores range from zero for no comorbidities, to 152, representing the highest comorbidity burden if all comorbidities were present and rated at the highest level of burden on daily life. Higher scores indicate a higher comorbidity burden.

The symptom perception subscale (SxP) has two components, including presence of physical and psychological symptoms and the effect of each symptom on daily life (bother). Presence is determined by a yes/no item that is scored as a "1" if the symptom is present. The symptom bother component is a four-point Likert scale ranging from "no bother" to "a great deal," and is designed to measure the impact of symptom distress. The symptom burden score includes 32 symptoms and is calculated by adding symptom-presence and symptom-bother scores. Total scores range from zero for no symptoms, to 96, with higher scores indicating higher symptom burden. The symptom attribution checklist includes a five-item list designed to collect data on the participants' perceptions

regarding the attribution of each symptom, including aging, cancer, cancer treatment, noncancer medications, and other explanations or a combination of attributions.

Evidence of Construct Validity

Pilot testing with a group of 62 older adult cancer survivors resulted in strong performance outcomes for COSMOS v2 in measuring both comorbidity burden and symptom perception. Both the CoB and SxP were administered to a group of 32 cancer survivors on active treatment and 30 cancer survivors who had been off treatment for 1 or more years. Data indicate that the CoB was able to detect differences between survivor groups with regard to the types of comorbidities reported by active-treatment and off-treatment participants. Although the CoB results indicated similar scores between groups, the off-treatment group reported significantly more thyroid problems ($p = .03$) and other chronic illnesses ($p = .005$). Similarly, the SxP scores were similar between groups; however, participants on active therapy reported significantly more nausea ($p = .045$), taste changes ($p = .006$), and body image disturbance ($p = .011$), which is expected in cancer survivors on active treatment. Although only three symptoms were identified as demonstrating statistical significance between groups, frequency of reported symptoms indicated that the symptoms of decreased sexual interest is a higher concern for survivors on active treatment than for those off treatment, and worry/anxiety/nervousness is a higher concern for off-treatment survivors than for those on active treatment. These results are congruent with reported clinical evidence in cancer survivorship and chronic illness literature.

Several items on the CoB (urinary incontinence, anxiety, depression, and trouble remembering) and corresponding items on the SxP (urinary symptoms, symptoms of

being worried or anxious, symptoms of feeling sad or blue, trouble remembering) were explored for potential measurement overlap. Within the CoB, depression and anxiety were found to be strongly associated (r = .652, p = .0001). Similarly, in the SxP, feeling sad and feeling anxious or nervous were also highly correlated (r = .997, p = .0001). However, both depression and anxiety had a minimal association between the two subscales (r = -.054, p = .67, and r = -.026, p = .84, respectively). The different reference time frames for measuring these chronic psychological conditions or symptoms illuminated a possible difference between subscales versus the within-subscale correlations. Additionally, the chronic condition of urinary incontinence and general urinary symptoms were found to have a minimal association (r = .115, p =.38), indicating that these items may be measuring different phenomena. Interestingly, the CoB item "trouble remembering things" and the SxP item "trouble remembering" were strongly associated (r = .638, p =.0001), suggesting that the same construct was being measured regardless of the time frame for measurement. These results support the specificity of each construct, comorbidity burden or symptom perception, to be uniquely measured while containing overlapping chronic conditions or symptoms. Further explanation of this overlap in variables requires cognitive interviewing to learn about participants' thought processes in evaluating these items as either chronic conditions or symptoms.

The symptom attribution descriptor scale was collapsed to three clinically relevant categories, including aging-related, cancer and treatment-related, and other. The symptom attribution scale demonstrated the ability to discriminate between groups, indicating a general shift in attribution from cancer and cancer-related for those on active treatment to aging and other for symptoms experienced by those off treatment. In general,

symptom attribution descriptions demonstrated the ability to discriminate between active-treatment and off-treatment participants, further supporting construct validity of the measure.

Reliability

Test-retest reliability for a subset of off-treatment participants was acceptable for both the CoB, with an intracorrelation coefficient (ICC) of .917, and the SxP, with an ICC of .696. The CoB subset results were expected based on the general stability of chronic conditions that are controlled. This finding is supported by test-retest data reported on common comorbidity measures used in oncology (Charlson, Szatrowski, Peterson, & Gold, 1994; Katz, Chang, Sandha, Fossel, & Bates, 1996). The SxP also demonstrated stability comparable to currently used symptom measures in oncology (Chang, Hwang, Feuerman, Kasimis, & Thaler, 2000; Stapleton, Holden, Epstein, & Wilkie, 2015).

Exploratory analysis of internal consistency of the CoB was measured by Cronbach's alpha, which resulted in a moderate reliability of .557. Interitem correlations for the CoB ranged from -.291 to .901. The wide range of item-to-item correlations reflects the heterogeneity of the construct of comorbidity burden. Most items did not demonstrate a strong overlap, with the exception of a small cluster of cardiac-related comorbidities including history of myocardial infarction and heart operation, history of heart failure and heart operation, and myocardial infarction and heart failure. Interestingly, there were several comorbidity-burden dyad correlations ranging from .348 to .701, with a significance level of .001 and higher. These dyads included anxiety and depression, gall bladder and pancreas problems, bleeding and arrhythmias, anemia and

other comorbidities, remembering and confusion, peptic ulcer disease and kidney problems, stroke and heart operation, obesity and asthma, diabetes and hypertension, and arrhythmias and kidney problems. These associated comorbidities suggest that there may be comorbidity clusters that have an effect on the measurement of overall comorbidity burden in cancer survivors. Exploratory analysis for internal consistency for the SxP resulted in a Cronbach's alpha of .731, which indicates acceptable reliability of the measure.

Summary of Pilot Results

The COSMOS v2 was piloted on 62 cancer survivors over 65 years old with two or more chronic illnesses or conditions and one reported symptom. Participants were stratified into two groups, including those on active treatment (n = 32) and those off treatment for 1 or more years (n = 30). Each participant completed a paper-and-pencil version of COSMOS in an average of 20 minutes (range 7–50 minutes). The typical study participant was a 72-year-old cancer survivor who was non-Hispanic, retired, living with a partner or spouse, and had some postsecondary education. Participants reported a cancer treatment history of receiving multiple modalities. Those participants in the active-treatment group were receiving one specific treatment type, including radiation therapy, chemotherapy, or long-term hormonal therapy. Data for the on-treatment group indicated that 78% had five or fewer survivorship years, while 70% the off-treatment group had more than 5 survivorship years. A broad range of cancer diagnoses were represented across each group. Breast and prostate cancer were highly represented, although not equally, within each group. More prostate cancer survivors were in the active-treatment group and more breast cancer survivors were in the off-treatment group.

Functional interference scores and current activity scores were similar across both groups, although a wide variance was noted in scores.

Both active- and off-treatment groups reported multiple chronic conditions. Active-treatment participants reported an average of 7.9 comorbidities (range 2–14) and an average CoB score of 17.1 (range 2–44). The off-treatment participants reported an average of 9.9 comorbidities (range 3–19) and an average CoB score of 21 (range 1–35). The most frequently reported chronic illnesses or conditions in both groups included arthritis, hypertension, incontinence, trouble remembering, and gastroesophageal reflux. Additionally, 50% or more of the off-treatment group also reported osteoporosis and problems with vision. Overall, off-treatment participants reported more chronic conditions than active-treatment participants (t = -2.48; p = .016); however, the CoB scores were not significantly different between groups (t = -1.83; p = .072).

Both groups reported similar numbers of symptoms, with active-treatment participants reporting an average of 10.3 and off-treatment participants reporting 9.8 (t = .42; p = .68). Both groups reported similar symptom-burden scores (t = .66; p = .51). The most frequently reported symptoms by both groups included lack of energy, pain, feeling drowsy, difficulty sleeping, urinary symptoms, feeling sad, dry mouth, numbness and tingling, and trouble remembering. Additionally, symptoms of itching and worry/anxiety/nervousness were reported by more than 50% of off-treatment participants.

Symptom-attribution data revealed some very interesting findings, which may illuminate the shift in symptom perception between older adults receiving active treatment and those who are beyond treatment. Symptom-attribution data were grouped into three clinically meaningful categories, including aging-related, cancer and cancer

treatment-related, and other, which includes noncancer medications; acute and chronic symptoms, illnesses, or conditions; psychological symptoms or conditions; behavior-related causes; or life activities. The off-treatment group most frequently attributed symptoms to aging-related causes or other causes. The active-treatment group most frequently attributed pain and trouble remembering to aging-related causes and lack of energy, feeling drowsy, and urinary symptoms to both aging-related and cancer-related causes. Difficulty sleeping was most frequently attributed to other causes by the active-treatment group. These results reflect an intuitive approach to symptom perception of cancer survivors either in active treatment or off treatment, and are similar to findings of a study of older adults with breast cancer (Heidrich et al., 2006).

Relationships between key variables of comorbidity burden, symptom perception, and functional interference were explored. Moderate correlation was found between comorbidity burden and symptom perception scores ($r = .46$, $p = .0001$). In addition, a moderate relationship was found between the symptom perception score and functional interference score ($r = .42$, $p = .001$), and a weak but significant relationship was found between the comorbidity burden score and the functional interference score ($r = .30$, $p = .05$). These results indicate that there may be key relationships between chronic conditions, symptoms, and physical functioning. Further exploration into these relationships is needed to explicate the impact of comorbidity burden and symptom perception on various dimensions of quality of life beyond physical functioning.

Several participants were interviewed regarding the ease of completing the scale; they agreed that the instructions were clear and the scale was easy to complete. In addition, interviewed participants described their own symptom appraisal process that

integrated their personal experiences with cancer, cancer treatment, chronic illness, and symptoms, and unique survivor-centered circumstances such as the social context of their experiences.

COSMOS v2 Revisions

Psychometric data indicate that revisions are needed for the CoB to enhance its validity as a patient-centered, clinically significant measure. Suggested revisions include consolidating or deleting several items (Lacasse, 2016a). Based on the pilot data and the current literature on symptom assessment in cancer survivors, the SxP will remain intact; however, the question related to symptom bother will be expanded to align with the current categories being used to assess symptoms in the Patient-Reported Outcomes Measurement Information System tools (Cella et al., 2010). The symptom-attribution list revealed three clinically meaningful categories when determining differences between cancer survivors on active treatment and those off treatment. The revised categories include aging-related, cancer-related, and other causes of symptoms. In addition, the question about the attribution of each reported symptom was reframed to encourage cancer survivors to choose the attribution, which is most likely causing each reported symptom.

In summary, data from this study indicate that self-report is a feasible method for measuring comorbidity burden and symptom perception in older adult cancer survivors. Insights into symptom attributions of cancer survivors at different stages of treatment and survivorship may inform clinical practice and the development of tailored educational and clinical interventions for cancer survivors.

Limitations

Sample Size

A sample size of 62 participants can be considered minimal for instrument development. Although a smaller sample size may contribute to an increased measurement error, a minimum representative sample of 12 to 30 participants per group from the population of interest is recommended for a pilot study for preliminary scale development in the medical field (Johanson & Brooks, 2010; Julius, 2005). It is suggested that a sufficient sample size of 10 participants for simple instrumentation issues such as clarity of instructions, item wording, and instrument administration issues is appropriate (Hertzog, 2008). The study sample yielded valuable data about the general performance of COMSOS, supporting construct validity and test-retest reliability and scale revisions.

Population Demographics

Due to the small sample size, further testing of the revised tool should be conducted with a broad range of older oncology patients, including specific racial groups and age stratifications (65–74, 75–85, >85 years). The population studied in this pilot does not fully represent the four most common cancers diagnosed in adults, including cancers of the lung and bronchus, prostate (men), breast (women), and colorectum (Miller et al., 2016). The active-therapy group does not fully represent the typical range of cancer-related treatments, such as chemotherapy and radiation therapy, which may affect the symptoms reported by this population. In addition, the study sample does not equally represent gender in the active- and off-treatment groups. This imbalance of gender representation may lead to missed opportunities for discovery of gender-specific

symptoms and symptom-attribution reporting patterns. Also, the tool should be tested in special populations, including frail elders and elderly adults with metastatic cancer. In addition, future testing in subpopulations of older adults with cancer may uncover specific issues such as varied response sets, word misinterpretation, and instrument fatigue. This study does provide general information about older adults living with multiple chronic illnesses including cancer and symptoms and important information for revisions of the COSMOS. The responses of participants in this study do provide a general perspective on comorbidity burden and the dimensions of symptom perception that are congruent with general cancer survivorship experiences (Hewitt, Greenfield, & Stovall, 2006; Institute of Medicine, 2012).

Time-Frame Reference for Assessment

The CoB includes two specific time frames for participants to consider regarding their history with chronic illness. Many questions in the subscale ask specifically if the participant has ever been diagnosed with a specific illness, although a cluster of questions is temporal in nature and asks about changes within the previous year. The SxP is focused on symptom recall over the previous month. This variation in the time period of recall may potentially affect the individual's accuracy of self-reporting chronic illnesses and symptoms. In addition, trouble remembering was reported by 50% or more participants, and this may also influence the accuracy of self-report. The temporal context of assessment frames critical perceptions of comorbidity burden and symptom perception. In the case of symptoms, it may be clinically relevant to capture the current symptom experience—within the previous week—to facilitate timely symptom management.

Recruitment Challenges

The study recruitment period extended over several years, 2010 through 2015, which may have had an impact on the results. Twenty-four percent of the cancer survivor population screened met the comorbidity eligibility criteria of having two or more chronic illnesses or conditions in addition to cancer, which is lower than the reported 33.2% in the general population of 65 years or older (Ward, Schiller, & Goodman, 2014); however, the time frame should have minimal impact on the CoB. The variable most likely to show the impact of the time frame for recruitment is the treatment type. Overall, cancer therapies for the study participants reflect the broad range of treatments currently available for cancer and its associated symptoms. Although results may have been influenced by the recruitment time frame, it is unlikely, based on the minimal differences found between active-therapy and off-treatment groups. In addition, results revealed that the general CoB and SxP scores were similar, but different specific symptoms and comorbidities were reported by active-treatment versus off-treatment participants, indicating instrument sensitivity.

Patient-Specific Treatment Variability

The scale was administered to a broad sample of older adult cancer survivors, which included multiple ages, cancer and treatment histories, and length of survivorship. In addition to the stratification of "active treatment versus off treatment," there were many emerging subgroups. Cancer treatment has evolved beyond the basic four treatment modalities (surgery, chemotherapy, radiation therapy, and biotherapy) and includes unique, patient-specific combinations of short- and long-term therapies. For example, long-term survivors may have a combination of surgery, chemotherapy, and radiation to

treat their initial diagnosis and then be prescribed a long-term treatment regimen (5 years or more) of hormonal therapy. Each treatment modality has a specific acute and chronic symptom trajectory, which is incorporated into the cancer survivor's chronic illness experiences. Further testing with purposeful sampling in treatment categories, age groups, and with various cancer and chronic illness clusters may illuminate scale sensitivities to specific populations. In addition, using a longitudinal or cross-sectional design may reveal more detailed tool sensitivities.

Frailty

Frail older adults often need assistance in completing lengthy assessment tools based on typical symptoms of frailty. The Balducci criteria for frailty are specific for gero-oncology patients and include the following elements: aged 85 years or older, dependence for one or more activities of daily living, three or more comorbidities, and one or more geriatric syndromes (Pal, Katheria, & Hurria, 2010). This study population had 3 participants who were over 85 years; all had cancer and two comorbidities, and two thirds reported at least one geriatric syndrome (incontinence). Although the study population may not meet all of the parameters for frailty, many participants have characteristics that may increase their frailty potential, including those who reported cognitive changes such as trouble remembering. This may have a negative impact on the reliability of the results in this population. Scales may need to be constructed to include alternative methods of delivery, with an emphasis on electronic reporting, which will facilitate communication with clinicians and allow for tracking of trends for comorbidity burden and symptom burden in frail oncology populations. The experiences with frail older adults who participated in the study provided valuable information about possible

supports needed to facilitate the completion of the scale.

Multiple Statistical Tests

Multiple statistical tests were used to analyze data collected for each subscale, functional interference scale, and demographics. The use of multiple statistical tests to detect the difference between groups may lead to a Type I error (Reid, 1983). This error may lead to detection of a statistically significant difference between groups when there actually is none. A Bonferroni correction may be used; however, this is a very conservative approach and would negate any significant findings and increase the likelihood of a Type II error (Polit & Beck, 2017). Another suggestion to prevent an increasing alpha is to decrease the level of significance to .01. In addition, when multiple dependent variables are analyzed in a serial fashion, the actual alpha may increase from multiple univariate tests. When multiple tests are conducted using a single data set, there is a risk of nonindependence due to the data coming from the same data participants (Reid, 1983). The exploratory nature of this study warrants a cautious interpretation of results regarding validity and reliability of COSMOS v2.

Implications

Clinical Practice

The COSMOS shows promise as a valid and reliable patient-centered measure for comorbidity burden and symptom perception in older adult cancer survivors. This instrument has the potential to yield clinically meaningful data to facilitate collaboration between cancer survivors and health care providers regarding survivor care and symptom management. The COSMOS may be a useful tool to integrate into a comprehensive

geriatric assessment and assist in screening for and monitoring of comorbidities and symptoms in cancer survivors. Clinicians can use the CoB and SxP as a baseline for collaboration with patients in building a dynamic information map in the electronic record to chart individual CoB and SxP pathways for clinical and self-management strategies. Information from the CoB and SxP also has the potential to be useful in adding key data to a comprehensive geriatric assessment, providing ongoing clinical outcome measures and planning survivorship care transitions.

Cancer survivors are being discharged from their oncologist's care with cancer survivorship care plans, which extend their ongoing care into the community as they transition to their primary care physicians. A valid, reliable, and consistent measure for comorbidity burden and symptom perception may assist in the communication of symptom assessment and treatment outcomes across patient care transitions. In addition, a standardized comorbidity and symptom measure provides valuable information for ongoing geriatric assessment and symptom screening of older cancer survivors and informs overall quality of life (Karlamangla et al., 2007).

In older adult cancer survivors, consistent serial symptom assessment using a database for trending may include sentinel symptoms that either herald emerging health changes or trigger a symptom cluster, which may have a profound effect on quality of life. Assessment of symptom attribution may also have an effect on assessment and treatment of general and specific symptoms during acute periods of cancer therapy. Employing the use of current technologies such as tablets or smart phones may increase patient reporting and assist with decisional support for comprehensive symptom management and detection of changes in health and well-being (Berry et al., 2014).

Because 53% of older adults use the Internet or email, one method of transitioning to digital reporting with older adults is to phase in the use of self-report technology, beginning with individuals who are technologically adept (Zickuhr & Madden, 2012).

Figure 7.1 depicts the proposed integration of COSMOS into a comprehensive geriatric assessment along the cancer survivorship trajectory. Following the initial diagnostic workup for individuals aged 65 and older, a standardized, comprehensive, geriatric screening assessment should be done to provide a pretreatment baseline for each cancer survivor (Horgan et al., 2012). The data collected can be reviewed by the interprofessional cancer care team and presented to the survivor to aid in decision making about treatment options. Furthermore, comorbidity burden, symptom perception, and symptom attribution should be tracked throughout the cancer survivorship experience to assist providers in developing individualized symptom management plans, guide transitions from cancer care to primary care, and coordinate ongoing care based on comorbidity burden, symptom perception, and symptom attribution. This information can also be used by nurses involved in coaching survivors through the various phases of survivorship, including early survivorship and extended survivorship (Economou, Hurria, & Grant, 2012; Overcash, 2015).

Research

Further testing of diagnosis-specific cancer survivor groups, including breast, prostate, lung, and colon cancer survivors, treatment-specific groups, and specific age groups, is needed to further expand the instrument's psychometric data. One recommendation is to use established measures to validate findings, including the Expectations of Aging Survey, which incorporates the dimensions of expected physical

Initial Cancer Diagnostic Workup
Initial Cancer Diagnosis and Treatment Discussion

↓

Further Diagnostic Data and Treatment Baseline
Comprehensive Geriatric Assessment Screening
for Patients Age 65 Years and Older

Critical Domains of Geriatric Assessment

Demographic Data	Polypharmacy	Functional Status (PROMIS)
Comorbidity measure (prognosis)	Comorbidity burden (baseline) COSMOS CoB	Nutrition (mini nutritional assessment)
Symptom perception [baseline] COSMOS	Symptom attribution [baseline] COSMOS SxP	Screening for geriatric syndromes not included in comorbidity burden measure
Cognition (MMSE or Mini-Cog measure)	Tilburg Frailty Indicator	Screening with Expectations of Aging measure

↓

Patient/family meeting with cancer care team to discuss data and make treatment decisions based on diagnostic data, geriatric assessment data, and patient preferences

↓

During the Active-Treatment Phase
Active-Treatment Geriatric Assessment
>>Symptom perception and attribution subscales
>>Develop a tailored, flexible symptom-management plan

↓

Cancer Survivorship—Posttreatment Phase
Posttreatment Comprehensive Integrative Assessment

Posttreatment Geriatric Assessment (posttreatment baseline and ongoing based on specific follow-up guidelines for primary cancer)
>>Cancer survivorship care plan development
>>Communication of cancer survivorship plan with primary care provider
>>Transition management to posttreatment cancer survivorship phase
>>Ongoing care coordination for high-risk older adult cancer survivors identified by geriatric assessment

Figure 7.1 Proposed integration of comprehensive geriatric assessment, COSMOS subscales, and phases of cancer survivorship. COSMOS = Comorbidity and Symptom Measure Oncology Scale; MMSE = Mini Mental Status Exam; PROMIS = Patient Reported Outcome Measurement Information System; and Mini-Cog = an assessment instrument for dementia.

and mental health, and cognitive functioning as one ages (Sarkisian, Steers, Hays, & Mangione, 2005). In addition, exploration of comorbidity burden clusters in cancer survivors has the potential to provide individualized treatment of chronic illnesses during and after primary cancer treatment and ongoing survivorship care. The COSMOS may also be useful in clinical research that focuses on the impact of comorbidity burden and symptoms in older adults with multiple chronic illnesses. In addition, this scale may be used to measure the effect of patient-centered and population-specific interventions aimed at minimizing both comorbidity and symptom burden.

Further exploration of the impact of symptom attribution on symptom-management outcomes is warranted. Symptom attribution may be critical in determining patient-specific health care behaviors and decision making. In addition, the exploration of symptom self-treatment within the context of comorbidities would be valuable to explore to determine self-care activities that are associated with symptom management in older adults with chronic illness, including cancer. The concepts of burden of chronic illness coupled with perceived symptoms and their attributions are challenging to measure; however, a valid and reliable measure of these interrelated concepts in cancer survivorship contributes to the overall understanding of the impact of comorbidities and symptoms on cancer survivors and provides valuable information for building systems of supportive care for both early and long-term cancer survivors.

Education

Geriatric assessment principles have been folded into advanced-practice education for family and adult nurse practitioners, clinical nurse specialists, and clinical nurse leaders (American Association of Colleges of Nursing, 2006). Specialty knowledge of the

impact of cancer history or active cancer treatment should be included as a major educational topic in entry-level and advanced-practice nursing education; there is also a need to integrate general principles of chronic illness and symptom assessment into interprofessional education programs. The critical use of population-specific assessment has the potential to lead to data-driven standards of care, which are patient-centered and enhance quality of life while living with chronic conditions and controlled symptoms.

Integrative symptom assessment/management is an emerging field, which can be incorporated into interprofessional education and practice. Traditional symptom assessment can be expanded to include body, mind, and spirit dimensions for each symptom assessed, in combination with primary attribution by the patient. Providers can use this patient-specific information coupled with current evidence for symptom management to deliver evidence-informed care based on science, population-based wisdom, and patient preferences.

Mentored practice opportunities for students and practicing nurses to learn comprehensive geriatric screening assessments and application of the results to patient-centered care is essential in translating research-based measures to clinical practice. Population-based comprehensive assessment of comorbidity and symptoms and treatment in older adult cancer survivors should also be a focus area in entry-level and advanced-practice education and ongoing staff development (American Association of Colleges of Nursing, 2006, 2008, 2011). Implementation of standardized measures of critical patient assessment parameters that are integrated into the electronic medical record and patient portal has the potential to enhance patient–provider relationships and increase precision health care of cancer survivors.

The discipline of nursing is strategically poised to make a major impact on symptom management and restoration of health and well-being. Distinguishing between chronic illness symptoms and cancer-related symptoms in older cancer survivors is critical to providing care focused on safe, quality outcomes, and principles of health promotion and risk reduction within the context of chronic illness management.

Health Care Policy

Information generated from COSMOS data may help inform clinicians who wish to shape policy on quality of life for cancer survivors and cancer survivorship care. Patient-centered information may also provide a clearer picture of the ongoing burden of illness on cancer survivors that in turn has the potential to impact chronic care reimbursement and care-delivery models. Current health care models are beginning to evolve to include innovative care coordination and transition management plans for older individuals requiring complex care. The early successes of these models demonstrate a positive impact on individual and population health, overall health care costs, and quality of life. The use of standardized patient-reported outcome measures coupled with insurance incentives may provide milestones for older adult cancer survivors to adhere to prescribed follow-up care and interventions to promote health restoration after cancer therapy.

The Oncology Care Model is an emerging care-delivery model focused on cost containment while maintaining high quality of oncology care (Thomas & Ward, 2016). This model is characterized as bundling care for medical oncology patients within a blended reimbursement model that integrates fee-for-service and shared-savings approaches. Services provided under this model include patient navigation,

comprehensive patient care planning, broad access to appropriate clinicians who have access to electronic medical records, adherence of treatments to national standards, and data-driven quality improvement. One area in which this general model may fall short is in the focus on the needs of older adults who are “complex” cancer survivors with multiple comorbidities and symptoms. Chronic illness and symptom management based on self-reported data should be streamlined into a shared electronic health record. It has the potential to allow health care providers to identify emerging issues in chronic illness and symptoms and intervene before a costly solution such as hospitalization is needed. In addition, older adults would benefit from having a documented comprehensive geriatric assessment on record to facilitate the delivery of care needed at each patient encounter while the patient is receiving active therapy.

Policies that support older adults with chronic illness as they age in place may benefit from a standardized approach to measuring the impact of comorbidity and symptoms. Both chronic illness and symptoms in cancer survivors may have a severe effect on their ability to maintain an optimal level of functioning. As the population continues to age, policies are needed to support optimal care, health, and well-being of those who are survivors of chronic illness, including cancer survivors.

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APPENDIX A

COSMOS VERSION 1

Chronic Illness and Symptom Survey

Directions:

This is a 2-part survey which asks questions about your personal health and symptoms that you might have. Please read the survey carefully and answer all of the questions to the best of your ability. If you feel uncomfortable answering a question, please skip the question.

Proposed Instrument: COSMOS Comorbidity Burden Subscale

Questions about your overall health

	Please check yes or no for each question.			If you checked yes, how much does this health problem affect your daily life? Check one box below.			
Question	Yes	No		Not at all	A little	Some	A great deal
1 .Have you ever had a heart attack or a heart operation?							
2. Have you ever had problems with your heartbeat?							
3. Have you ever had a blood clot in your leg?							
4. Have you ever been diagnosed or treated for high blood pressure?							
5. Have you ever had a stroke?							
6. Have you ever had trouble moving one side of your body or both your legs for more than 24 hours?							
7. Have you ever been diagnosed or treated for a stomach ulcer?							
8. Has a doctor ever told you that you have liver problems?							
9. Have you ever had a bowel problem such as chronic diarrhea or a blockage (other than constipation)?							
10. Have you ever been diagnosed or treated for high blood sugar (diabetes)?							

Questions about your overall health

	Please check yes or no for each question.			If you checked yes, how much does this health problem affect your daily life? Check one box below.			
Question	Yes	No		Not at all	A little	Some	A great deal
11. Have you ever been diagnosed or treated for a thyroid problem?							
12. Have you ever been diagnosed with kidney trouble?							
13. Have you ever needed kidney dialysis or received a kidney transplant?							
14. Have you ever been diagnosed or treated for brittle bones or osteoporosis?							
15. Have you ever been diagnosed or treated for arthritis?							
16. Have you ever been diagnosed or treated for lupus?							
17. Have you ever been diagnosed or treated for behavior problems?							
18. Have you ever been overweight by 50 pounds or more?							
19. Have you ever been diagnosed or treated for depression?							
20. Have you ever been diagnosed or treated for anxiety?							
21. Have you ever been diagnosed with another type of cancer?							

Questions about your overall health during the past year

	Please check yes or no for each question.			If you checked yes, how much does this health problem affect your daily life? Check one box below.			
Question	Yes	No		Not at all	A little	Some	A great deal
22. Have you been diagnosed with heart failure?							
23. Have you had problems with poor blood flow in your arms, legs, or feet?							
24. Have you had trouble breathing while you are sitting quietly?							
25. Have you had trouble breathing while you are moving around?							
26. Have you been treated for breathing problems?							
27. Have you had severe indigestion after meals or at bedtime?							
28. Have you had a problem with your gallbladder or pancreas?							
29. Have you had long periods of forgetfulness or felt disoriented?							
30. Have you walked with a shuffle or had a trembling head or hands?							
31. Have you had broken bones or a broken hip?							
32. Have you had problems with your eyes which affect your vision?							

Questions about your overall health during the past year

	Please check yes or no for each question.			If you checked yes, how much does this health problem affect your daily life? Check one box below.			
Question	Yes	No		Not at all	A little	Some	A great deal
33. Have you had problems with your hearing?							
34. Have you had problems with your balance?							
35. Have you had many (more than 5) infections?							
36. Have you had a bleeding problem?							
37. Have you had a low red blood cell count?							

Proposed Instrument: COSMOS Symptom Perception Subscale

Questions about symptoms

Below is a list of symptoms, if you had any of the following symptoms **during the past month,** please check **yes**.

				If you checked **yes**, how much did the symptom **distress or bother** you? Check **one** box below.				If you checked **yes,** then check any of the following statements that apply.				
Symptom	Yes	No		None OR A little	Some	A great deal		I think that this symptom is **caused by aging.**	I think that this symptom is **caused by my cancer.**	I think that this symptom is **caused by my cancer treat-ments.**	I think that this symptom is **caused by my medicines for non-cancer conditions** .	I think that this symptom has some other cause. ***Please write in what you think is causing the symptom.**
1. Difficulty concentrating												
2. Trouble remembering												
3. Pain												
4. Lack of energy												
5. Cough												
6.Changes in skin												
7. Dry Mouth												

Questions about symptoms

Below is a list of symptoms, if you had any of the following symptoms **during the past month,** please check **yes**.

				If you checked **yes**, how much did the symptom **distress or bother** you? Check **one** box below.				If you checked **yes,** then check any of the following statements that apply.				
Symptom	Yes	No		None OR A little	Some	A great deal		I think that this symptom is **caused by aging.**	I think that this symptom is **caused by my cancer.**	I think that this symptom is **caused by my cancer treat-ments.**	I think that this symptom is **caused by my medicines for non-cancer conditions** .	I think that this symptom has some other cause. ***Please write in what you think is causing the symptom.**
8. Nausea												
9. Feeling drowsy												
10. Numbness/ tingling in hands or feet												
11. Difficulty sleeping												
12. Feeling bloated												

Questions about symptoms

Below is a list of symptoms, if you had any of the following symptoms **during the past month,** please check **yes**.

				If you checked **yes**, how much did the symptom **distress or bother** you? Check **one** box below.				If you checked **yes,** then check any of the following statements that apply.				
Symptom	Yes	No		None OR A little	Some	A great deal		I think that this symptom is **caused by aging.**	I think that this symptom is **caused by my cancer.**	I think that this symptom is **caused by my cancer treat-ments.**	I think that this symptom is **caused by my medicines for non-cancer conditions** .	I think that this symptom has some other cause. ***Please write in what you think is causing the symptom.**
13. Problems with urination												
14. Vomiting												
15. Shortness of breath												
16. Sweats												
17. Hot Flashes												
18. Hot Flushes												

Questions about symptoms

Below is a list of symptoms, if you had any of the following symptoms **during the past month,** please check **yes**.

				If you checked **yes**, how much did the symptom **distress or bother** you? Check **one** box below.				If you checked **yes,** then check any of the following statements that apply.				
Symptom	Yes	No		None OR A little	Some	A great deal		I think that this symptom is **caused by aging.**	I think that this symptom is **caused by my cancer.**	I think that this symptom is **caused by my cancer treat-ments.**	I think that this symptom is **caused by my medicines for non-cancer conditions** .	I think that this symptom has some other cause. ***Please write in what you think is causing the symptom.**
19. Problems with sexual interest or activity												
20. Itching												
21. Lack of appetite												
22. Dizziness												
23. Difficulty swallowing												

Questions about symptoms

Below is a list of symptoms, if you had any of the following symptoms **during the past month,** please check **yes**.

				If you checked **yes**, how much did the symptom **distress or bother** you? Check **one** box below.				If you checked **yes,** then check any of the following statements that apply.				
Symptom	Yes	No		None OR A little	Some	A great deal		I think that this symptom is **caused by aging.**	I think that this symptom is **caused by my cancer.**	I think that this symptom is **caused by my cancer treat-ments.**	I think that this symptom is **caused by my medicines for non-cancer conditions** .	I think that this symptom has some other cause. ***Please write in what you think is causing the symptom.**
24. Mouth sores												
25. Change in the way food tastes												
26. Weight loss												
27. Hair loss												
28. Constipation												

Questions about symptoms

Below is a list of symptoms, if you had any of the following symptoms **during the past month,** please check **yes**.

				If you checked **yes**, how much did the symptom **distress or bother** you? Check **one** box below.				If you checked **yes,** then check any of the following statements that apply.				
Symptom	Yes	No		None OR A little	Some	A great deal		I think that this symptom is **caused by aging.**	I think that this symptom is **caused by my cancer.**	I think that this symptom is **caused by my cancer treat-ments.**	I think that this symptom is **caused by my medicines for non-cancer conditions** .	I think that this symptom has some other cause. ***Please write in what you think is causing the symptom.**
29. Diarrhea												
30. "I don't look like myself"												
31. Worrying												
32. Feeling irritable												
33. Feeling anxious												
34. Feeling nervous												

Questions about symptoms

Below is a list of symptoms, if you had any of the following symptoms **during the past month,** please check **yes**.

				If you checked **yes**, how much did the symptom **distress or bother** you? Check **one** box below.				If you checked **yes,** then check any of the following statements that apply.				
Symptom	Yes	No		None OR A little	Some	A great deal		I think that this symptom is **caused by aging.**	I think that this symptom is **caused by my cancer.**	I think that this symptom is **caused by my cancer treat-ments.**	I think that this symptom is **caused by my medicines for non-cancer conditions** .	I think that this symptom has some other cause. ***Please write in what you think is causing the symptom.**
1.												
2.												
3.												

APPENDIX B

EXPERT PANEL RECRUITMENT LETTER

July 6, 2006

Dear _____,

I am a doctoral student the PhD Distance Education Program with a Focus in Cancer Research at The University of Utah College of Nursing. I am developing an instrument to measure comorbidity burden and symptom perception in older adults with cancer. Symptom perception in older adults may be influenced by many issues such as expectations of the normal aging process, comorbidities, treatments for chronic illnesses, and functional status. Valid and reliable measures of unique dimensions of symptom perception in older adults will assist health care providers in assessing and planning comprehensive symptom management and help clinical researchers to evaluate clinically significant interventions for older adults with cancer. The next step in the instrument development process is to establish content validity through the use of an expert panel.

You have been identified as a content expert in oncology, gerontology, or both and are invited to participate on an expert panel of clinicians and researchers to assist in validating the content of this new instrument. Your participation in the instrument review process will be invaluable as a preliminary step in developing a valid and reliable instrument for comprehensive symptom assessment in the context of current comorbidities in the older adult cancer population. Participation in this panel includes the review of a 37-item comorbidity burden subscale and a 34-item symptom perception subscale. You will be asked to judge the individual item relevancy to each subscale and the overall item representation of the specific domain of the subscale. In addition, you will be asked to suggest improvements in the format, directions for completing the scale, additions and deletions of items, clarity of items, and overall comprehensiveness of the measure. It is anticipated that this instrument review will take approximately 30 – 45 minutes to complete within a time frame of two weeks after you receive the review materials.

If you are interested in participating on this expert panel please contact me at clacasse@nursing.arizona.edu. I look forward to hearing from you by July 15, 2006. You will receive a follow-up email or call if I do not hear from you. Thank you for your consideration in being a participant on this expert panel.

Cheryl Lacasse, MS, RN, OCN®
Doctoral Candidate
University of Utah College of Nursing
and
Associate Clinical Professor
University of Arizona College of Nursing

APPENDIX C

EXPERT PANEL REVIEW PACKET

August 1, 2006

Dear _____,

Thank you for agreeing to participate on an expert panel of clinicians and researchers to assist in validating the content of a newly developed instrument to measure comorbidity burden and symptom perception in older adults with cancer. The Comorbidity and Symptom Measurement in Oncology Scale (COSMOS) includes 2 subscales: a 37-item comorbidity burden subscale and a 34-item symptom perception subscale. Please review and comment on each individual item's relevancy to each subscale and the overall item representativeness to the specific domain of each subscale using the Expert Panel Review Form. In addition, please suggest improvements in the format, directions for scale completion, addition and deletions of items, clarity of items, and overall comprehensiveness of the measure. It is anticipated that this instrument review will take approximately 30 – 45 minutes to complete within a time frame of three weeks after you receive the review materials. Each subscale and the Expert Panel Review Form is attached to this email and can be completed and returned electronically.

Thank you for being a participant on this expert panel. I look forward to receiving your review and comments on the COSMOS by August 22, 2006. You will receive a follow-up email reminder close to this date. If you have any questions about the instrument review process, please contact me at clacasse@nursing.arizona.edu.

Cheryl Lacasse, MS, RN, OCN®
Doctoral Student
University of Utah College of Nursing
and
Associate Clinical Professor
University of Arizona College of Nursing

Expert Panel Review Form of Comorbidity and Symptom Measurement in Oncology Scale (COSMOS) ver. 1.0

COMORBIDITY BURDEN SUBSCALE

Comorbidity burden is defined as a combination of the presence of multiple chronic illnesses and the interference of each illness with general daily life.

Please review each item in the scale for its relevancy to the content of the scale based on the above definition of the construct.

Also comment on the instructions for completing the tool, overall layout, and appropriateness for the target population.

****Please comment on the overall format of the Comorbidity Burden subscale as presented below.**

Questions about your overall health

Please check yes or no for each question.
If you checked **yes**, how much does this health problem effect your daily life?
Check **one** box below.

Question	Yes	No		Not at all	A little	Some	A great deal
1 .Have you ever had a heart attack or a heart operation?							
2. Have you ever had problems with your heartbeat?							
3. Have you ever had a blood clot in your leg?							
4. Have you ever been diagnosed or treated for high blood pressure?							

<u>Please comment on the following:</u>**

- Are the directions for completing the tool clear?

- If not, what are your suggestions for improvement?

Please rate the relevancy of each item on the Comorbidity Burden subscale by checking a rating (1–4) as described below.

Item (Comorbidity Burden)	Item is not relevant (1)	Unable to assess relevance without item revision OR item is in need of such revision that it is no longer relevant (2)	Item is relevant but needs minor alteration (3)	Item is very relevant and succinct (4)	Comments about item or suggestions for item revision.
1. Have you ever had a heart attack or a heart operation?					
2. Have you ever had problems with your heartbeat?					
3. Have you ever had a blood clot in your leg?					
4. Have you ever been diagnosed or treated for high blood pressure?					
5. Have you ever had a stroke?					
6. Have you ever had trouble moving one side of your body or both your legs for more than 24 hours?					
7. Have you ever been diagnosed or treated for a stomach ulcer?					

Please rate the relevancy of each item on the Comorbidity Burden subscale by checking a rating (1 – 4) as described below.

Item (Comorbidity Burden)	Item is not relevant	Unable to assess relevance without item revision OR item is in need of such revision that it is no longer relevant	Item is relevant but needs minor alteration	Item is very relevant and succinct	Comments about item or suggestions for item revision
8. Has a doctor you ever told you that you have liver problems?					
9. Have you ever had a bowel problem such as chronic diarrhea or a blockage (other than constipation)?					
10. Have you ever been diagnosed or treated for high blood sugar (diabetes)?					
11. Have you ever been diagnosed or treated for a thyroid problem?					
12. Have you ever been diagnosed with kidney trouble?					
13. Have you ever needed kidney dialysis or received a kidney transplant?					
14. Have you ever been diagnosed or treated for brittle bones or osteoporosis?					

Please rate the relevancy of each item on the Comorbidity Burden subscale by checking a rating (1 – 4) as described below.

Item (Comorbidity Burden)	Item is not relevant (1)	Unable to assess relevance without item revision OR item is in need of such revision that it is no longer relevant (2)	Item is relevant but needs minor alteration (3)	Item is very relevant and succinct (4)	Comments about item or suggestions for item revision.
15. Have you ever been diagnosed or treated for arthritis?					
16. Have you ever been diagnosed or treated for lupus?					
17. Have you ever been diagnosed or treated for behavior problems?					
18. Have you ever been overweight by 50 pounds or more?					
19. Have you ever been diagnosed or treated for depression?					
20. Have you ever been diagnosed or treated for anxiety?					
21. Have you ever been diagnosed with more than one type of cancer?					

Please rate the relevancy of each item on the Comorbidity Burden subscale by checking a rating (1 – 4) as described below.

*Also, please comment on the appropriateness of the time frame *"over the past year"* for the items in the above section.

Item (Comorbidity Burden) **Over the past year**	Item is not relevant (1)	Unable to assess relevance without item revision OR item is in need of such revision that it is no longer relevant (2)	Item is relevant but needs minor alteration (3)	Item is very relevant and succinct (4)	Comments about item or suggestions for item revision
22. Have you had problems with heart failure?					
23. Have you had problem with poor blood flow in your arms or legs?					
24. Have you had trouble breathing while you are sitting quietly?					
25. Have you had trouble breathing while you are moving around?					
26. Have you been treated for breathing problems?					
27. Have you had severe indigestion after meals or at bedtime?					
28. Have you had a problem with your gallbladder or pancreas?					

29. Have you had long periods of forgetfulness or felt disoriented?					
Item (Comorbidity Burden) **Over the past year**	Item is not relevant (1)	Unable to assess relevance without item revision OR item is in need of such revision that it is no longer relevant (2)	Item is relevant but needs minor alteration (3)	Item is very relevant and succinct (4)	Comments about item or suggestions for item revision.
30. Have you walked with a shuffle or had a trembling head or hands?					
31. Have you had broken bones or a broken hip?					
32. Have you had problems with your eyes which affect your vision?					
33. Have you had problems with your hearing?					
34. Have you had problems with your balance?					
35. Have you had many (more than 5) infections?					
36. Have you had a bleeding problem?					
37. Have you had a low red blood cell count?					

Are there any critical omissions from the Comorbidity Burden subscale? **Yes** **No**
If so, please describe.

Please comment on the overall format of the tool in relationship to the target population of older adults 65 years and older.

Please describe any general comments or concerns that you have about the Comorbidity Burden subscale?

SYMPTOM PERCEPTION SUBSCALE

Symptom Perception is defined as a combination of the level of bother of a symptom and the client's perception of its cause.

Please review each item in the scale for its relevancy to the content of the scale based on the above definition of the construct.

Of note, this symptom list was adapted with permission from the Memorial Symptom Assessment Scale Short Form (MSAS-SF).

Also comment on the instructions for completing the tool, overall layout, and appropriateness for the target population.

***Symptom Perception Subscale: Please comment on the overall format of this symptom scale as presented below.**

Questions about symptoms
Below is a list of symptoms, if you had any of the following symptoms **during the past month,** please check **yes**.

If you checked **yes**, how much did the symptom **distress or bother** you?
If you checked **yes,** then check any of the following statements that apply.
Check **one** box below.

Symptom	Yes	No		None OR A little	Some	A great deal		I think that this symptom is **caused by aging.**	I think that this symptom is **caused by my cancer.**	I think that this symptom is **caused by my cancer treat-ments.**	I think that this symptom is **caused by my medicines for non-cancer conditions**.	I think that this symptom has some other cause. ***Please write in what you think is causing the symptom.**
1. Difficulty concentrating												
2. Trouble remembering												
3. Pain												

<u>*Please address the following:</u>

- Are the directions for completing the tool clear? If not, what are suggestions for improvement?

- Are the areas of symptom perception clear and relevant? If not, what are suggestions for improvement?

Please rate the relevancy of each item on the Symptom Perception subscale by checking a rating (1 – 4) as described below.

Item (Symptom)	Item is not relevant (1)	Unable to assess relevance without item revision OR item is in need of such revision that it is no longer relevant (2)	Item is relevant but needs minor alteration (3)	Item is very relevant and succinct (4)	Comments about item or suggestions for item revision.
1. Difficulty concentrating					
2. Trouble remembering					
3. Pain					
4. Lack of energy					
5. Cough					
6. Changes in skin					
7. Dry mouth					
8. Nausea					

Please rate the relevancy of each item on the Symptom Perception subscale by checking a rating (1 – 4) as described below.

Item (Symptom)	Item is not relevant (1)	Unable to assess relevance without item revision OR item is in need of such revision that it is no longer relevant (2)	Item is relevant but needs minor alteration (3)	Item is very relevant and succinct (4)	Comments about item or suggestions for item revision.
9. Feeling drowsy					
10. Numbness/ tingling in hands or feet					
11. Difficulty sleeping					
12. Feeling bloated					
13. Problems with urination					
14. Vomiting					
15. Shortness of breath					

Please rate the relevancy of each item on the Symptom Perception subscale by checking a rating (1 – 4) as described below.

Item (Symptom)	Item is not relevant (1)	Unable to assess relevance without item revision OR item is in need of such revision that it is no longer relevant (2)	Item is relevant but needs minor alteration (3)	Item is very relevant and succinct (4)	Comments about item or suggestions for item revision
16. Sweats					
17. Hot flashes					
18. Hot flushes					
19. Problems with sexual interest or activity					
20. Itching					
21. Lack of appetite					
22. Dizziness					
23. Difficulty swallowing					

Please rate the relevancy of each item on the Symptom Perception subscale by checking a rating (1 – 4) as described below.

Item (Symptom)	Item is not relevant (1)	Unable to assess relevance without item revision OR item is in need of such revision that it is no longer relevant (2)	Item is relevant but needs minor alteration (3)	Item is very relevant and succinct (4)	Comments about item or suggestions for item revision.
24. Mouth sores					
25. Change in the way food tastes					
26. Weight loss					
27. Hair loss					
28. Constipation					
29. Diarrhea					
30. “I don’t look like myself”					
31. Worrying					

Please rate the relevancy of each item on the Symptom Perception subscale by checking a rating (1 – 4) as described below.

Item (Symptom)	Item is not relevant (1)	Unable to assess relevance without item revision OR item is in need of such revision that it is no longer relevant (2)	Item is relevant but needs minor alteration (3)	Item is very relevant and succinct (4)	Comments about item or suggestions for item revision.
32. Feeling irritable					
33. Feeling anxious					
34. Feeling nervous					

****Please comment on the overall format of the "other symptoms" scale as presented below.**

Questions about symptoms

Below is a list of symptoms, if you had any of the following symptoms **during the past month,** please check **yes**.

If you checked **yes**, how much did the symptom **distress or bother** you? Check **one** box below.	If you checked **yes,** then check any of the following statements that apply.

Symptom	Yes	No		None OR A little	Some	A great deal		I think that this symptom is **caused by aging.**	I think that this symptom is **caused by my cancer.**	I think that this symptom is **caused by my cancer treat-ments.**	I think that this symptom is **caused by my medicines for non-cancer conditions**.	I think that this symptom has some other cause. ***Please write in what you think is causing the symptom.**
1.												
2.												
3.												

If you had any other symptoms **during the PAST MONTH**, please **list them below.**

<u>Please address the following:</u>**

Are the directions for completing the tool clear? If not, what are suggestions for improvement?

Are there any critical omissions from the Symptom Perception subscale? _____Yes _____No
If so, please describe.

Please comment on the overall format of the tool in relationship to the target population of older adults 65 years and older.

Please describe any general comments or concerns that you have about the Symptom Perception subscale?

Thank you for your participation in this project. Your contributions will be very valuable to the further development of this measurement tool.

APPENDIX D

COSMOS VERSION 2

Chronic Illness and Symptom Survey
Part 1

Directions:

This is a two-part survey which asks questions about your health, illnesses, and symptoms. Please read the survey carefully and answer all of the questions to the best of your ability. If you feel uncomfortable answering a question, skip that question and move on to the next question.

1. Have you ever had a heart attack? _____Yes _____No **<u>If you answered yes</u>**, Please answer the question on the right. →	How much does this affect your current daily life? (Check **<u>one</u>**.) ☐ Not at all ☐ A little ☐ Some ☐ A great deal
2. Have you ever needed a heart operation (to repair heart vessels or heart valves)? _____Yes _____No **<u>If you answered yes</u>**, Please answer the question on the right. →	How much does this problem affect your current daily life? (Check **<u>one</u>**.) ☐ Not at all ☐ A little ☐ Some ☐ A great deal
3. Have you ever had an irregular heartbeat that needed medications or a pacemaker? _____Yes _____No **<u>If you answered yes</u>**, Please answer the question on the right. →	How much does this affect your current daily life? (Check **<u>one</u>**.) ☐ Not at all ☐ A little ☐ Some ☐ A great deal
4. Over the past year, have you been told by a health care provider that you have heart failure? _____Yes _____No **<u>If you answered yes</u>**, Please answer the question on the right. →	How much does this affect your current daily life? (Check **<u>one</u>**.) ☐ Not at all ☐ A little ☐ Some ☐ A great deal
5. Over the past year, have you been told by a health care provider that you have high blood pressure? _____Yes _____No **<u>If you answered yes</u>**, Please answer the question on the right. →	How much does this health problem affect your current daily life? (Check **<u>one</u>**.) ☐ Not at all ☐ A little ☐ Some ☐ A great deal

6. Have you ever had a problem with blood clots in your arms, legs, or lungs? _____Yes _____No **<u>If you answered yes</u>**, Please answer the question on the right. →	How much does this affect your current daily life? (Check **<u>one</u>**.) ☐ Not at all ☐ A little ☐ Some ☐ A great deal
7. Over the past year, have you been told by a health care provider that you have poor circulation in your arms and legs? _____Yes _____No **<u>If you answered yes</u>**, Please answer the question on the right. →	How much does this health problem affect your current daily life? (Check **<u>one</u>**.) ☐ Not at all ☐ A little ☐ Some ☐ A great deal
8. Have you ever had a stroke? _____Yes _____No **<u>If you answered yes</u>**, Please answer the question on the right. →	How much does this health problem affect your current daily life? (Check **<u>one</u>**.) ☐ Not at all ☐ A little ☐ Some ☐ A great deal
9. Have you ever been told by a health care provider that you have asthma? _____Yes _____No **<u>If you answered yes</u>**, Please answer the question on the right. →	How much does this health problem affect your current daily life? (Check **<u>one</u>**.) ☐ Not at all ☐ A little ☐ Some ☐ A great deal
10. Have you ever been told by a health care provider that you have COPD or chronic lung disease? _____Yes _____No **<u>If you answered yes</u>**, Please answer the question on the right. →	How much does this health problem affect your current daily life? (Check **<u>one</u>**.) ☐ Not at all ☐ A little ☐ Some ☐ A great deal
11. Have you ever been told by a health care provider that you have an ulcer? _____Yes _____No **<u>If you answered yes</u>**, Please answer the question on the right. →	How much does this health problem affect your current daily life? (Check **<u>one</u>**.) ☐ Not at all ☐ A little ☐ Some ☐ A great deal

12. Over the past year, have you had indigestion or heartburn after meals or at bedtime? _____Yes _____No **If you answered yes**, Please answer the question on the right. →	How much does this health problem affect your current daily life? (Check **one**.) ☐ Not at all ☐ A little ☐ Some ☐ A great deal
13. Over the past year, have you been told by a health care provider that you have a gall bladder problem? _____Yes _____No **If you answered yes**, Please answer the question on the right. →	How much does this health problem affect your current daily life? (Check **one**.) ☐ Not at all ☐ A little ☐ Some ☐ A great deal
14. Over the past year, have you been told by a health care provider that you have a problem with your pancreas (not diabetes)? _____Yes _____No **If you answered yes**, Please answer the question on the right. →	How much does this health problem affect your current daily life? (Check **one**.) ☐ Not at all ☐ A little ☐ Some ☐ A great deal
15. Have you ever been told by a health care provider that you have high blood sugar or diabetes? _____Yes _____No **If you answered yes**, Please answer the question on the right. →	How much does this health problem affect your current daily life? (Check **one**.) ☐ Not at all ☐ A little ☐ Some ☐ A great deal
16. Have you ever been told by a health care provider that you have liver problems? _____Yes _____No **If you answered yes**, Please answer the question on the right. →	How much does this health problem affect your current daily life? (Check **one**.) ☐ Not at all ☐ A little ☐ Some ☐ A great deal
17. Have you ever had a bowel problem (other than constipation) such as chronic diarrhea or a blockage? _Yes _____No **If you answered yes**,	How much does this health problem affect your current daily life? (Check **one**.) ☐ Not at all ☐ A little ☐ Some ☐ A great deal

Please answer the question on the right. →	
18. Have you ever been told by a health care provider that you have kidney trouble? _____Yes _____No **<u>If you answered yes</u>**, Please answer the question on the right. →	How much does this health problem affect your current daily life? (Check **<u>one</u>**.) ☐ Not at all ☐ A little ☐ Some ☐ A great deal
19. Over the past year, have you had a problem with urine leaking out before or after you go to the bathroom? _____Yes _____No **<u>If you answered yes</u>**, Please answer the question on the right. →	How much does this health problem affect your current daily life? (Check **<u>one</u>**.) ☐ Not at all ☐ A little ☐ Some ☐ A great deal
20. Have you ever been told by a health care provider that you have a thyroid problem? _____Yes _____No **<u>If you answered yes</u>**, Please answer the question on the right. →	How much does this health problem affect your current daily life? (Check **<u>one</u>**.) ☐ Not at all ☐ A little ☐ Some ☐ A great deal
21. Have you ever been told by a health care provider that you have two or more different types of cancer (not cancer that has spread to another place in the body)? _____Yes _____No **<u>If you answered yes</u>**, Please answer the question on the right. →	How much does this health problem affect your current daily life? (Check **<u>one</u>**.) ☐ Not at all ☐ A little ☐ Some ☐ A great deal
22. Have you ever been told by a health care provider that you have arthritis? _____Yes _____No **<u>If you answered yes</u>**, Please answer the question on the right. →	How much does this health problem affect your current daily life? (Check **<u>one</u>**.) ☐ Not at all ☐ A little ☐ Some ☐ A great deal

23. Have you ever been told by a health care provider that you have osteoporosis, weakened bones, or bone loss? _____Yes _____No **<u>If you answered yes</u>**, Please answer the question on the right. →	How much does this health problem affect your current daily life? (Check **<u>one</u>**.) ☐ Not at all ☐ A little ☐ Some ☐ A great deal
24. Have you ever had a knee or hip replacement? _____Yes _____No **<u>If you answered yes</u>**, Please answer the question on the right. →	How much does this health problem affect your current daily life? (Check **<u>one</u>**.) ☐ Not at all ☐ A little ☐ Some ☐ A great deal
25. Over the past year, have you had any broken bones or a broken hip? _____Yes _____No **<u>If you answered yes</u>**, Please answer the question on the right. →	How much does this health problem affect your current daily life? (Check **<u>one</u>**.) ☐ Not at all ☐ A little ☐ Some ☐ A great deal
26. Over the past year, have you had problems with your balance that has caused you to trip or fall? _____Yes _____No **<u>If you answered yes</u>**, Please answer the question on the right. →	How much does this health problem affect your current daily life? (Check **<u>one</u>**.) ☐ Not at all ☐ A little ☐ Some ☐ A great deal
27. Over the past year, have you walked with a shuffle or had trembling hands or other body parts most of the time? _____Yes _____No **<u>If you answered yes</u>**, Please answer the question on the right. →	How much does this health problem affect your current daily life? (Check **<u>one</u>**.) ☐ Not at all ☐ A little ☐ Some ☐ A great deal

28. Over the past year, have you had trouble remembering things? _____Yes _____No **<u>If you answered yes</u>**, Please answer the question on the right. →	How much does this health problem affect your current daily life? (Check **<u>one</u>**.) ☐ Not at all ☐ A little ☐ Some ☐ A great deal
29. Over the past year, have you had mixed up or confusing thoughts? _____Yes _____No **<u>If you answered yes</u>**, Please answer the question on the right. →	How much does this health problem affect your current daily life? (Check **<u>one</u>**.) ☐ Not at all ☐ A little ☐ Some ☐ A great deal
30. Have you ever been diagnosed and treated for depression? _____Yes _____No **<u>If you answered yes</u>**, Please answer the question on the right. →	How much does this health problem affect your current daily life? (Check **<u>one</u>**.) ☐ Not at all ☐ A little ☐ Some ☐ A great deal
31. Have you ever been diagnosed and treated for anxiety of nervousness? _____Yes _____No **<u>If you answered yes</u>**, Please answer the question on the right. →	How much does this health problem affect your current daily life? (Check **<u>one</u>**.) ☐ Not at all ☐ A little ☐ Some ☐ A great deal
32. Have you ever been overweight by 50 pounds or more? _____Yes _____No **<u>If you answered yes</u>**, Please answer the question on the right. →	How much does this health problem affect your current daily life? (Check **<u>one</u>**.) ☐ Not at all ☐ A little ☐ Some ☐ A great deal
33. Over the past year, have you had any problems with your eyes that affect your general vision? _____Yes _____No **<u>If you answered yes</u>**, Please answer the question on the right. →	How much does this health problem affect your current daily life? (Check **<u>one</u>**.) ☐ Not at all ☐ A little ☐ Some ☐ A great deal

34. Over the past year, have you had any major changes in your hearing? _____Yes _____No **<u>If you answered yes</u>**, Please answer the question on the right. →	How much does this health problem affect your current daily life? (Check **<u>one</u>**.) ☐ Not at all ☐ A little ☐ Some ☐ A great deal
35. Over the past year, have you had many (more than 5) infections such as urinary tract or kidney infections and lung infections? _____Yes _____No **<u>If you answered yes</u>**, Please answer the question on the right. →	How much does this health problem affect your current daily life? (Check **<u>one</u>**.) ☐ Not at all ☐ A little ☐ Some ☐ A great deal
36. Over the past year, have you had a bleeding problem that needed medication or some other treatment? _____Yes _____No **<u>If you answered yes</u>**, Please answer the question on the right. →	How much does this health problem affect your current daily life? (Check **<u>one</u>**.) ☐ Not at all ☐ A little ☐ Some ☐ A great deal

37. Over the past year, have you had anemia (a low red blood cell count)? _____Yes _____No **<u>If you answered yes</u>**, Please answer the question on the right. →	How much does this health problem affect your current daily life? (Check **<u>one</u>**.) ☐ Not at all ☐ A little ☐ Some ☐ A great deal
38. FOR WOMEN ONLY: Over the past year, have you had any problems with your uterus or ovaries that needed the care of a health care provider? _____Yes _____No **<u>If you answered yes</u>**, Please answer the question on the right. →	How much does this health problem affect your current daily life? (Check **<u>one</u>**.) ☐ Not at all ☐ A little ☐ Some ☐ A great deal
38. FOR MEN ONLY: Over the past year, have you had any prostate problems such as difficulty passing urine or pain passing urine? _____Yes _____No **<u>If you answered yes</u>**, Please answer the question on the right. →	How much does this health problem affect your current daily life? (Check **<u>one</u>**.) ☐ Not at all ☐ A little ☐ Some ☐ A great deal
39. If you have any other chronic illness or condition that has not been listed, please list below: _____ _____ _____	How much do these health problems affect your current daily life? (Check **<u>one</u>**.) ☐ Not at all ☐ A little ☐ Some ☐ A great deal

*Please record the amount of time that it took for you to complete this section:_____min

Thank you for completing this section of the survey.

The next section of the survey continues on the next page.

Chronic Illness and Symptom Survey
Part 2

Directions:

This is a two-part survey which asks questions about your health, illnesses, and symptoms. Please read the survey carefully and answer all of the questions to the best of your ability. If you feel uncomfortable answering a question, skip that question and move on to the next question.

1. **During the past month**, have you had difficulty concentrating? _____Yes _____No **If you answered yes**, please answer the questions to the right. →	1b. How much does this symptom bother you? ___None OR a little ___Some ___A great deal 1c. Check any of the following statements that you think are true about your symptom of difficulty concentrating. ___ It is caused by aging. ___It is caused by my cancer. ___It is caused by my cancer treatments. ___It is caused by my medicines for non-cancer conditions. ___This symptom has some other cause. (Write in what you think is causing the symptom.)
2. **During the past month**, have you had trouble remembering? _____Yes _____No **If you answered yes**, please answer the questions to the right. →	2b. How much does this symptom bother you? ___None OR a little ___Some ___A great deal 2c. Check any of the following statements that you think are true about your symptom having trouble remembering. ___It is caused by aging. ___It is caused by my cancer. ___It is caused by my cancer treatments. ___It is caused by my medicines for non-cancer conditions. ___This symptom has some other cause. (Write in what you think is causing the symptom.)
3. **During the past month**, have you had pain? _____Yes _____No **If you answered yes**, please answer the questions to the right. →	3b. How much does this symptom bother you? ___None OR a little ___Some ___A great deal 3c. Check any of the following statements that you think are true about your symptom of pain. ___It is caused by aging. ___It is caused by my cancer. ___It is caused by my cancer treatments. ___It is caused by my medicines for non-cancer conditions. ___This symptom has some other cause. (Write in what you think is causing the symptom.)

4. **During the past month**, have you had fatigue or lack of energy? _____Yes _____No **If you answered yes**, please answer the questions to the right. →	4b. How much does this symptom bother you? ___None OR a little ___Some ___A great deal 4c. Check any of the following statements that you think are true about your symptom of fatigue. ___It is caused by aging. ___It is caused by my cancer. ___It is caused by my cancer treatments. ___It is caused by my medicines for non-cancer conditions. ___This symptom has some other cause. (Write in what you think is causing the symptom.)
5. **During the past month**, have you had a cough? _____Yes _____No **If you answered yes**, please answer the questions to the right. →	5b. How much does this symptom bother you? ___None OR a little ___Some ___A great deal 5c. Check any of the following statements that you think are true about your symptom of having a cough. ___It is caused by aging. ___It is caused by my cancer. ___It is caused by my cancer treatments. ___It is caused by my medicines for non-cancer conditions. ___This symptom has some other cause. (Write in what you think is causing the symptom.)
6. **During the past month**, have you had skin changes (such as altered skin color, thin or fragile skin, reddened skin or rash)? _____Yes _____No **If you answered yes**, please answer the questions to the right. →	6b. How much does this symptom bother you? ___None OR a little ___Some ___A great deal 6c. Check any of the following statements that you think are true about your symptom of skin changes. ___It is caused by aging. ___It is caused by my cancer. ___It is caused by my cancer treatments. ___It is caused by my medicines for non-cancer conditions. ___This symptom has some other cause. (Write in what you think is causing the symptom.)

7. **During the past month**, have you had a dry mouth? _____Yes _____No **If you answered yes**, please answer the questions to the right. →	7b. How much does this symptom bother you? ___None OR a little ___Some ___A great deal 7c. Check any of the following statements that you think are true about your symptom of having a dry mouth. ___It is caused by aging. ___It is caused by my cancer. ___It is caused by my cancer treatments. ___It is caused by my medicines for non-cancer conditions. ___This symptom has some other cause. (Write in what you think is causing the symptom.)
8. **During the past month**, have you had nausea? _____Yes _____No **If you answered yes**, please answer the questions to the right. →	8b. How much does this symptom bother you? ___None OR a little ___Some ___A great deal 8c. Check any of the following statements that you think are true about your symptom of nausea. ___It is caused by aging. ___It is caused by my cancer. ___It is caused by my cancer treatments. ___It is caused by my medicines for non-cancer conditions. ___This symptom has some other cause. (Write in what you think is causing the symptom.)
9. **During the past month**, have you had vomiting? _____Yes _____No **If you answered yes**, please answer the questions to the right. →	9b. How much does this symptom bother you? ___None OR a little ___Some ___A great deal 9c. Check any of the following statements that you think are true about your symptom of vomiting. ___It is caused by aging. ___It is caused by my cancer. ___It is caused by my cancer treatments. ___It is caused by my medicines for non-cancer conditions. ___This symptom has some other cause. (Write in what you think is causing the symptom.)

10. **During the past month**, have you had a feeling of being drowsy? _____Yes _____No **If you answered yes**, please answer the questions to the right. →	10b. How much does this symptom bother you? ___None OR a little ___Some ___A great deal 10c. Check any of the following statements that you think are true about your symptom of being drowsy. ___It is caused by aging. ___It is caused by my cancer. ___It is caused by my cancer treatments. ___It is caused by my medicines for non-cancer conditions. ___This symptom has some other cause. (Write in what you think is causing the symptom.)
11. **During the past month**, have you had numbness/ tingling in hands or feet? _____Yes _____No **If you answered yes**, please answer the questions to the right. →	11b. How much does this symptom bother you? ___None OR a little ___Some ___A great deal 11c. Check any of the following statements that you think are true about your symptom of numbness and tingling. ___It is caused by aging. ___It is caused by my cancer. ___It is caused by my cancer treatments. ___It is caused by my medicines for non-cancer conditions. ___This symptom has some other cause. (Write in what you think is causing the symptom.)
12. **During the past month**, have you had difficulty sleeping? _____Yes _____No **If you answered yes**, please answer the questions to the right. →	12b. How much does this symptom bother you? ___None OR a little ___Some ___A great deal 12c. Check any of the following statements that you think are true about your symptom of having difficulty sleeping. ___It is caused by aging. ___It is caused by my cancer. ___It is caused by my cancer treatments. ___It is caused by my medicines for non-cancer conditions. ___This symptom has some other cause. (Write in what you think is causing the symptom.)

13. **During the past month**, have you had a feeling of being bloated? _____Yes _____No **If you answered yes**, please answer the questions to the right. →	13b. How much does this symptom bother you? ___None OR a little ___Some ___A great deal 13c. Check any of the following statements that you think are true about your symptom feeling bloated. ___It is caused by aging. ___It is caused by my cancer. ___It is caused by my cancer treatments. ___It is caused by my medicines for non-cancer conditions. ___This symptom has some other cause. (Write in what you think is causing the symptom.)
14. **During the past month**, have you had urinary problems (such as going often, pain, leaking)? _____Yes _____No **If you answered yes**, please answer the questions to the right. →	14b. How much does this symptom bother you? ___None OR a little ___Some ___A great deal 14c. Check any of the following statements that you think are true about your symptom of urinary problems. ___It is caused by aging. ___It is caused by my cancer. ___It is caused by my cancer treatments. ___It is caused by my medicines for non-cancer conditions. ___This symptom has some other cause. (Write in what you think is causing the symptom.)
15. **During the past month**, have you had shortness of breath? _____Yes _____No **If you answered yes**, please answer the questions to the right. →	15b. How much does this symptom bother you? ___None OR a little ___Some ___A great deal 15c. Check any of the following statements that you think are true about your symptom of shortness of breath. ___It is caused by aging. ___It is caused by my cancer. ___It is caused by my cancer treatments. ___It is caused by my medicines for non-cancer conditions. ___This symptom has some other cause. (Write in what you think is causing the symptom.)

16. **During the past month**, have you had sweating which is not normal for you? _____Yes _____No **If you answered yes**, please answer the questions to the right. →	16b. How much does this symptom bother you? ___None OR a little ___Some ___A great deal 16c. Check any of the following statements that you think are true about your symptom of sweating. ___It is caused by aging. ___It is caused by my cancer. ___It is caused by my cancer treatments. ___It is caused by my medicines for non-cancer conditions. ___This symptom has some other cause. (Write in what you think is causing the symptom.)
17. **During the past month**, have you had hot flashes or hot flushes? _____Yes _____No **If you answered yes**, please answer the questions to the right. →	17b. How much does this symptom bother you? ___None OR a little ___Some ___A great deal 17c. Check any of the following statements that you think are true about your symptom of hot flashes or hot flushes. ___It is caused by aging. ___It is caused by my cancer. ___It is caused by my cancer treatments. ___It is caused by my medicines for non-cancer conditions. ___This symptom has some other cause. (Write in what you think is causing the symptom.)
18. **During the past month**, have you had problems with sexual interest or activity? _____Yes _____No **If you answered yes**, please answer the questions to the right. →	18b. How much does this symptom bother you? ___None OR a little ___Some ___A great deal 18c. Check any of the following statements that you think are true about your symptom of problems with sexual interest or activity. ___It is caused by aging. ___It is caused by my cancer. ___It is caused by my cancer treatments. ___It is caused by my medicines for non-cancer conditions. ___This symptom has some other cause. (Write in what you think is causing the symptom.)

19. **During the past month**, have you had itching? _____Yes _____No **If you answered yes**, please answer the questions to the right. →	19b. How much does this symptom bother you? ___None OR a little ___Some ___A great deal 19c. Check any of the following statements that you think are true about your symptom of itching. ___It is caused by aging. ___It is caused by my cancer. ___It is caused by my cancer treatments. ___It is caused by my medicines for non-cancer conditions. ___ This symptom has some other cause. (Write in what you think is causing the symptom.)
20. **During the past month**, have you had a lack of appetite? _____Yes _____No **If you answered yes**, please answer the questions to the right. →	20b. How much does this symptom bother you? ___None OR a little ___Some ___A great deal 20c. Check any of the following statements that you think are true about your symptom of lack of appetite. ___It is caused by aging. ___It is caused by my cancer. ___It is caused by my cancer treatments. ___It is caused by my medicines for non-cancer conditions. ___This symptom has some other cause. (Write in what you think is causing the symptom.)
21. **During the past month**, have you had dizziness? _____Yes _____No **If you answered yes**, please answer the questions to the right. →	21b. How much does this symptom bother you? ___None OR a little ___Some ___A great deal 21c. Check any of the following statements that you think are true about your symptom of dizziness. ___It is caused by aging. ___It is caused by my cancer. ___It is caused by my cancer treatments. ___It is caused by my medicines for non-cancer conditions ___This symptom has some other cause. (Write in what you think is causing the symptom.)

22. **During the past month**, have you had difficulty swallowing? _____Yes _____No **If you answered yes**, please answer the questions to the right. →	22b. How much does this symptom bother you? ___None OR a little ___Some ___A great deal 22c. Check any of the following statements that you think are true about your symptom of difficulty swallowing. ___It is caused by aging. ___It is caused by my cancer. ___It is caused by my cancer treatments. ___It is caused by my medicines for non-cancer conditions ___This symptom has some other cause. (Please write in what you think is causing the symptom.)
23. **During the past month**, have you had mouth sores? _____Yes _____No **If you answered yes**, please answer the questions to the right. →	23b. How much does this symptom bother you? ___None OR a little ___Some ___A great deal 23c. Check any of the following statements that you think are true about your symptom of mouth sores. ___It is caused by aging. ___It is caused by my cancer. ___It is caused by my cancer treatments. ___It is caused by my medicines for non-cancer conditions. ___This symptom has some other cause. (Write in what you think is causing the symptom.)
24. **During the past month**, have you had changes in the way food tastes? _____Yes _____No **If you answered yes**, please answer the questions to the right. →	24b. How much does this symptom bother you? ___None OR a little ___Some ___A great deal 24c. Check any of the following statements that you think are true about your symptom of taste changes. ___It is caused by aging. ___It is caused by my cancer. ___It is caused by my cancer treatments. ___It is caused by my medicines for non-cancer conditions. ___This symptom has some other cause. (Write in what you think is causing the symptom.)

25. **During the past month**, have you had unexpected weight loss? _____Yes _____No **If you answered yes**, please answer the questions to the right. →	25b. How much does this symptom bother you? ___None OR a little ___Some ___A great deal 25c. Check any of the following statements that you think are true about your symptom of unexpected weight loss. ___It is caused by aging. ___It is caused by my cancer. ___It is caused by my cancer treatments. ___It is caused by my medicines for non-cancer conditions. ___This symptom has some other cause. (Write in what you think is causing the symptom.)
26. **During the past month**, have you had hair loss? _____Yes _____No **If you answered yes**, please answer the questions to the right. →	26b. How much does this symptom bother you? ___None OR a little ___Some ___A great deal 26c. Check any of the following statements that you think are true about your symptom of hair loss. ___It is caused by aging. ___It is caused by my cancer. ___It is caused by my cancer treatments. ___It is caused by my medicines for non-cancer conditions. ___This symptom has some other cause. (Write in what you think is causing the symptom.)
27. **During the past month**, have you had constipation? _____Yes _____No **If you answered yes**, please answer the questions to the right. →	27b. How much does this symptom bother you? ___None OR a little ___Some ___A great deal 27c. Check any of the following statements that you think are true about your symptom of constipation. ___It is caused by aging. ___It is caused by my cancer. ___It is caused by my cancer treatments. ___It is caused by my medicines for non-cancer conditions. ___This symptom has some other cause. (Write in what you think is causing the symptom.)

28. **During the past month**, have you had diarrhea? _____Yes _____No **If you answered yes**, please answer the questions to the right. →	28b. How much does this symptom bother you? ___None OR a little ___Some ___A great deal 28c. Check any of the following statements that you think are true about your symptom of diarrhea. ___It is caused by aging. ___It is caused by my cancer. ___It is caused by my cancer treatments. ___It is caused by my medicines for non-cancer conditions. ___This symptom has some other cause. (Write in what you think is causing the symptom.)
29. **During the past month**, have you had a feeling that "I don't look like myself"? _____Yes _____No **If you answered yes**, please answer the questions to the right. →	29b. How much does this symptom bother you? ___None OR a little ___Some ___A great deal 29c. Check any of the following statements that you think are true about your symptom of feeling that you don't look like yourself. ___It is caused by aging. ___It is caused by my cancer. ___It is caused by my cancer treatments. ___It is caused by my medicines for non-cancer conditions. ___This symptom has some other cause. (Write in what you think is causing the symptom.)
30. **During the past month**, have you been worried, anxious, or nervous? _____Yes _____No **If you answered yes**, please answer the questions to the right. →	30b. How much does this symptom bother you? ___None OR a little ___Some ___A great deal 30c. Check any of the following statements that you think are true about your symptom of being worried, anxious, or nervous. ___It is caused by aging. ___It is caused by my cancer. ___It is caused by my cancer treatments. ___It is caused by my medicines for non-cancer conditions. ___This symptom has some other cause. (Write in what you think is causing the symptom.)

31. **During the past month**, have you had a feeling of being irritable? _____Yes _____No **If you answered yes**, please answer the questions to the right. →	31b. How much does this symptom bother you? ___None OR a little ___Some ___A great deal 31c. Check any of the following statements that you think are true about your symptom of feeling irritable. ___It is caused by aging. ___It is caused by my cancer. ___It is caused by my cancer treatments. ___It is caused by my medicines for non-cancer conditions. ___This symptom has some other cause. (Write in what you think is causing the symptom.)
32. **During the past month**, have you had a feeling of being sad or blue? _____Yes _____No **If you answered yes**, please answer the questions to the right. →	32b. How much does this symptom bother you? ___None OR a little ___Some ___A great deal 32c. Check any of the following statements that you think are true about your symptom of feeling sad or blue. ___It is caused by aging. ___It is caused by my cancer. ___It is caused by my cancer treatments. ___It is caused by my medicines for non-cancer conditions. ___This symptom has some other cause. (Write in what you think is causing the symptom.)
33. **During the past month**, have you had other symptoms not listed in this survey? _____Yes _____No **If you answered yes**, please list the symptoms below and answer the questions to the right. →	33b. How much do these symptoms bother you? ___None OR a little ___Some ___A great deal 33c. Check any of the following statements that you think are true about your other symptoms. ___It is caused by aging. ___It is caused by my cancer. ___It is caused by my cancer treatments. ___It is caused by my medicines for non-cancer conditions. ___This symptom has some other cause. (Write in what you think is causing the symptom.)

Thank you for your time in completing this survey.

APPENDIX E

GENERAL INFORMATION QUESTIONNAIRES

General Information Questionnaire

Directions: Please answer all of these questions accurately. The information you provide will be used only for this project and will not be seen by anyone else.

1. Today's date: _____/_____/_____
   month day year

2. Your age: _____ (years)

3. Your gender: _____(1) Male _____(2) Female

4. Your ethnic background (select one):
   _____ (1) Hispanic, Latino, or of Spanish Origin
   _____ (2) Not Hispanic or Latino

5. Your racial background (select one or more):
   _____ (1) Asian
   _____ (2) Black or African American
   _____ (3) Native Hawaiian or Other Pacific Islander
   _____ (4) American Indian or Alaska Native
   _____ (5) White

6. Your marital status:
   _____ (1) Single (never married)
   _____ (2) Separated or divorced
   _____ (3) Widow or widower
   _____ (4) Married

7. Current living situation:
   _____ (1) I live alone.
   _____ (2) I live with my spouse/ partner.
   _____ (3) I live with my adult son/ daughter.
   _____ (4) I live with an adult relative other than my son or daughter.
   _____ (5) I live with my children under the age of 18.
   _____ (6) Other (Please describe)
   _____

8. Highest grade of school you completed:
   _____ (1) Less than 6th grade
   _____ (2) 6th - 8th grade
   _____ (3) Some high school
   _____ (4) High school graduate
   _____ (5) Technical school graduate
   _____ (6) Some college
   _____ (7) College graduate
   _____ (8) Postgraduate /Professional degree

9. What best describes your employment status?
   _____ (1) Full-time
   _____ (2) Part-time
   _____ (3) Unemployed
   _____ (4)Retired
   _____ (5)Full-time homemaker

10. Are you a religious person?
   _____ (1)Yes
   _____ (2) No

11. What is your religion?
   _____ (1) Catholic
   _____ (2) Protestant
   _____ (3) Jewish
   _____ (4) Latter Day Saint
   _____ (5) Greek Orthodox
   _____ (6) Muslim
   _____ (7) Other _____
   _____ (8) None

12. How spiritual of a person would you describe yourself to be?
   _____ (1) Not at all spiritual
   _____ (2) Slightly spiritual
   _____ (3) Moderately spiritual
   _____ (4) Quite spiritual
   _____ (5) Very spiritual

13. What is your household income before taxes?
   _____ (1) Under $10,000
   _____ (2) $10,000-$19,999
   _____ (3) $20,000-$29,999
   _____ (4) $30,000-$39,999
   _____ (5) $40,000-$49,999
   _____ (6) $50,000-$59,999
   _____ (7) $60,000-$79,999
   _____ (8) $80,000-$99,999
   _____ (9) $100,000 or more

14. What are your present sources of financial support? Check all that apply.
   _____ (1) Savings
   _____ (2) Retirement
   _____ (3) Stock/bonds
   _____ (4) Family support
   _____ (5) Social Security
   _____ (6) Welfare
   _____ (7) Employment
   _____ (8) Other (please specify)
   _____

15. How would you describe the adequacy of your current financial situation?
    _____ (1) I have problems making ends meet.
    _____ (2) My financial situation is comfortable.
    _____ (3) My income is more than adequate to meet my needs.

16. What type of health insurance do you have?
    _____ (1) Medicare
    _____ (2) Medicaid
    _____ (3) Other (please specify)_____
    _____ (4) None

19. Please *circle* only one number that best describes your **current** activity level.
    0 I have normal activity without symptoms.
    1 I have some symptoms, but I do not need to spend any extra time resting during the day.
    2 I need some time to rest (e.g., in bed), but it amounts to less than half of my normal daytime.
    3 I need to rest (e.g., in bed) for more than half of my normal daytime.
    4 I am unable to get out of bed.

20. What (if any) medications do you take? Please list below.

Name or Type of Medicine	How often do you take this medicine?
1.	
2.	
3.	
4.	
5.	
6.	
7.	
8.	
9.	
10.	
11.	
12.	

The next brief set of questions is about **your cancer and treatment history**. Please answer them as accurately as possible. The information that you provide will be used only for this project and will not be seen by anyone else.

21. What kind of cancer have you been diagnosed with? (please check any that apply)

_____ Breast Cancer
_____ Prostate Cancer
_____ Lung Cancer
_____ Colorectal Cancer
_____ Lymphoma
_____ Melanoma
_____ Another kind:
please describe_____

22. When were you diagnosed with cancer?

_____(month) and _____ (year)

23. What type of **treatment have you received for your cancer**?

A. Surgery _____Yes _____No **If you answered yes**, Please answer the questions to the right. →	What kind of surgery did you have? When did you have your surgery?
B. Chemotherapy _____Yes _____No **If you answered yes**, Please answer the questions to the right. →	When did you start chemotherapy? When did this treatment end?
C. Radiation Therapy _____Yes _____No **If you answered yes**, Please answer the questions to the right. →	When did you have your radiation therapy? How many days or weeks did the treatment last?
D. Hormonal Therapy _____Yes _____No **If you answered yes**, Please answer the questions to the right. →	When did you start this therapy? How long were you on this therapy?
E. Another kind of therapy: please describe_____ _____ _____Yes _____No **If you answered yes**, Please answer the questions to the right. →	When did you start this treatment/ therapy? When did this treatment/ therapy end?

General Information Questionnaire - 2

Directions: Please answer all of these questions accurately. The information you provide will be used only for this project and will not be seen by anyone else.

1. Today's date: _____/_____/_____

   month day year

2. Current living situation:

   _____ (1) I live alone.
   _____ (2) I live with my spouse/ partner.
   _____ (3) I live with my adult son/ daughter.
   _____ (4) I live with an adult relative other than my son or daughter.
   _____ (5) I live with my children under the age of 18.
   _____ (6) Other
(Please describe)_____

3. What best describes your employment status?

   _____ (1) Full-time
   _____ (2) Part-time
   _____ (3) Unemployed
   _____ (4) Retired
   _____ (5) Full-time homemaker

4. Please *circle* only one number that best describes your **current** activity level.

   0 I have normal activity without symptoms.
   1 I have some symptoms, but I do not need to spend any extra time resting during the day.
   2 I need some time to rest (e.g., in bed), but it amounts to less than half of my normal daytime.
   3 I need to rest (e.g., in bed) for more than half of my normal daytime.
   4 I am unable to get out of bed.

APPENDIX F

SAMPLE QUESTIONS FOR SEMISTRUCTURED INTERVIEW

Sample Questions for Semistructured Interview

(Questions will be asked about each subscale separately)

Context of Comorbidities

1	*Were the instructions for the section that asked about your overall health (symptoms) clear? -If not, what might help to make them clearer?
2	*Please comment on the length of this section. –Was it too long, too short or just right? -How did you feel after completing this section? -What questions about your health did this section bring up for you?
3	*Were there any questions in that section that were confusing, difficult to understand, or difficult to answer? -If so, which questions were they and why did they seem difficult to answer?
4	*Did you skip any questions in that section? -If yes, why did you skip those questions?

Sample Questions Related to Perception of Symptoms in the Older Adult

1	*When you think about the symptoms that you have, what types of things do you think about? -What types of things do you think about or do before you tell you healthcare provider about your symptoms?
2	*When you think about your symptoms, do you try to figure out what is causing them? -What is the usual reason that your symptoms occur?
3	*Do you think that the other diseases that you have or take medicine for effect how you think about your symptoms? -If yes, what has the most effect on your symptoms and why?
4	*Do you have any comments about the tool or thoughts about how you think about your symptoms?
5	*How do your symptoms affect your ability to do daily activities? -How do your other diseases affect your ability to do daily activities?

APPENDIX G

PARTICIPANT RECRUITMENT LETTER

COSMOS STUDY
Comorbidity & Symptom Measurement - Oncology

Dear _____,

My name is Cheryl Lacasse and I am a doctoral student at the University of Utah College of Nursing. I have been an oncology nurse for over 20 years. I am conducting a research study which will help health care providers to understand the relationship between cancer, symptoms, and ongoing medical conditions and how each person thinks about them.

Many cancer survivors have symptoms during and after treatment which may be caused by cancer, its treatment or other medical conditions. These symptoms may be difficult to measure and may have a great impact on the quality of life of cancer survivors. This study will help to determine if a newly developed survey will provide valuable information about symptoms and ongoing medical conditions in older cancer patients to health care providers. This information may help health care providers to work with cancer survivors to improve their quality of life.

You have been identified as a potential participant in this study either through an initial screening process in collaboration with your health care provider or by your personal interest.

Individuals are eligible for this study if they:

- Are 65 years old or older
- Have ever been diagnosed with cancer
- Are currently receiving treatment for cancer OR have been off of cancer treatment for at least one year
- Have 2 or more ongoing medical conditions (such as high blood pressure, arthritis, heart disease, lung disease, diabetes, or others)
- At least one symptom (such as pain, feeling tired, difficulty sleeping, lack of appetite or others)
- Can read, write, and understand English.

Participation in this study involves 2 steps: 1) a brief 10 minute discussion with a researcher to assess your eligibility for the study and 2) completing a survey and 2 brief questionnaires and a brief interview.

Participation in this study is voluntary. Please notify me within 2 weeks of receiving this letter if you are interested in learning more about this study. You can call me at 1 – 520 – 429 – 1172 and leave a message. I will return your call as soon as possible. If I haven't heard from you within 2 weeks, you will receive a follow-up phone call to answer any questions you might have about the study and give you an opportunity to indicate if you are interested in participating in the study. If you are not interested in participating in the study, please call the phone number above and request that no further contact be made.

Thank you for considering participation in this study.
Sincerely,
Cheryl Lacasse, MS, RN, OCN
Doctoral Student, University of Utah College of Nursing

APPENDIX H

PARTICIPANT LETTER FOR TEST-RETEST PACKET

Dear Participant,

Thank you for participating in the ***Co-morbidity and Symptom Measurement in Older Adults with Cancer (COSMOS)*** study.

The purpose of this research study is to try a new survey which asks you about the effect of your health and illness on your everyday life and your thoughts about symptoms. We are doing this study to determine if the survey will provide helpful information about chronic illness and symptoms in older cancer patients to healthcare providers.

You are receiving this mailing because you have previously completed a survey and questionnaires similar to those enclosed. Please complete the enclosed survey and questionnaires and return them in the enclosed self-addressed stamped envelope.

There are no known risks involved in participating in this study. It is possible that some people may become distressed from thinking about their health, illness, and symptoms. If you become distressed, we can give you information about individuals who may be able to help you with this.

There is no direct benefit to you for your participation. However, you may gain a deeper understanding of the relationship between your disease experience and your symptoms. This may help you to talk with your health care providers more effectively about your symptoms. You may also assist health care providers to learn more about the general relationship between chronic illness and symptoms which may have a positive impact on the overall disease management plan.

Each set of surveys and questionnaires will be assigned a specific code which will not be directly associated with any of your personal identifying information. All of your information will be entered into a database using the assigned code. The Principal Investigator will assign the specific code and maintain this information in a locked file cabinet. The collected data will be coded and may be viewed by a research assistant and other research collaborators.

If you have any questions, concerns, or complaints or if you feel you have been harmed by this research please contact Cheryl Lacasse, Doctoral student, University of Utah College of Nursing at 520 – 626 – 6321.

Contact the Institutional Review Board (IRB) if you have questions regarding your rights as a research participant. Also, contact the IRB if you have questions, complaints or concerns which you do not feel you can discuss with the investigator. The University of Utah IRB may be reached by phone at (801) 581-3655 or by e-mail at irb@hsc.utah.edu.

It should take about 15 to 20 minutes to complete the enclosed questionnaires. Participation in this study is voluntary. You can choose not to take part and you can also choose not to finish the survey and questionnaires or omit any question you prefer not to answer without penalty or loss of benefits.

By returning this questionnaire in the envelope provided, you are giving your consent to participate.

Thank you for your time and participation in this study.

APPENDIX I

COSMOS VERSION 3

Chronic Illness and Symptom Survey
Part 1

Directions:

This is a two-part survey which asks questions about your health, illnesses, and symptoms. Part One has questions about chronic illness and conditions.

Please read the survey carefully and answer all of the questions to the best of your ability. If you feel uncomfortable answering a question, skip that question and move on to the next question.

1. Have you ever been told by a health care provider that you have any heart conditions such as a heart attack, heart valve problems, or coronary artery disease? _____No _____Yes **<u>If you answered yes</u>**, please answer the question on the right.	How much does this health problem affect your current daily life? (Check **<u>one</u>**.) ☐ Not at all ☐ A little bit ☐ Somewhat ☐ Quite a bit ☐ Very much
2. Have you ever been told by a health care provider that you have an irregular heartbeat? _____No _____Yes **<u>If you answered yes</u>**, please answer the question on the right.	How much does this health problem affect your current daily life? (Check **<u>one</u>**.) ☐ Not at all ☐ A little bit ☐ Somewhat ☐ Quite a bit ☐ Very much
3. Have you ever been told by a health care provider that you have heart failure? _____No _____Yes **<u>If you answered yes</u>**, please answer the question on the right.	How much does this health problem affect your current daily life? (Check **<u>one</u>**.) ☐ Not at all ☐ A little bit ☐ Somewhat ☐ Quite a bit ☐ Very much
4. Have you ever been told by a health care provider that you have high blood pressure or are you taking medicine for high blood pressure? _____No _____Yes **<u>If you answered yes</u>**, please answer the question on the right.	How much does this health problem affect your current daily life? (Check **<u>one</u>**.) ☐ Not at all ☐ A little ☐ Somewhat ☐ Quite a bit ☐ Very much
5. Have you ever had a problem with blood clots in your arms, legs, or lungs? _____No _____Yes **<u>If you answered yes</u>**, please answer the question on the right.	How much does this health problem affect your current daily life? (Check **<u>one</u>**.) ☐ Not at all ☐ A little ☐ Somewhat ☐ Quite a bit ☐ Very much

6. Have you ever been told by a health care provider that you have poor circulation in your arms and legs? _____No _____Yes **<u>If you answered yes</u>**, please answer the question on the right. →	How much does this health problem affect your current daily life? (Check **<u>one</u>**.) ☐ Not at all ☐ A little ☐ Somewhat ☐ Quite a bit ☐ Very much
7. Have you ever had a stroke or a TIA (mini stroke)? _____No _____Yes **<u>If you answered yes</u>**, please answer the question on the right. →	How much does this health problem affect your current daily life? (Check **<u>one</u>**.) ☐ Not at all ☐ A little ☐ Somewhat ☐ Quite a bit ☐ Very much
8. Have you ever been told by a health care provider that you have a chronic lung condition such as asthma or COPD? _____No _____Yes **<u>If you answered yes</u>**, please answer the question on the right. →	How much does this health problem affect your current daily life? (Check **<u>one</u>**.) ☐ Not at all ☐ A little ☐ Somewhat ☐ Quite a bit ☐ Very much
9. Have you ever had indigestion or heartburn after meals or at bedtime? _____No _____Yes **<u>If you answered yes</u>**, please answer the question on the right. →	How much does this health problem affect your current daily life? (Check **<u>one</u>**.) ☐ Not at all ☐ A little ☐ Somewhat ☐ Quite a bit ☐ Very much
10. Have you ever been told by a health care provider that you had an ulcer? _____No _____Yes **<u>If you answered yes</u>**, please answer the question on the right. →	How much does this health problem affect your current daily life? (Check **<u>one</u>**.) ☐ Not at all ☐ A little ☐ Somewhat ☐ Quite a bit ☐ Very much

11. Have you ever been told by a health care provider that you had problems with your gall bladder? _____No _____Yes **<u>If you answered yes</u>**, please answer the question on the right.	How much does this health problem affect your current daily life? (Check **<u>one</u>**.) ☐ Not at all ☐ A little ☐ Somewhat ☐ Quite a bit ☐ Very much
12. Have you ever been told by a health care provider that you have any problems with your liver or pancreas (not diabetes)? _____No _____Yes **<u>If you answered yes</u>**, please answer the question on the right.	How much does this health problem affect your current daily life? (Check **<u>one</u>**.) ☐ Not at all ☐ A little ☐ Somewhat ☐ Quite a bit ☐ Very much
13. Have you ever had a bowel problem (other than constipation) such as chronic diarrhea or a blockage? _____No _____Yes **<u>If you answered yes</u>**, please answer the question on the right.	How much does this health problem affect your current daily life? (Check **<u>one</u>**.) ☐ Not at all ☐ A little ☐ Somewhat ☐ Quite a bit ☐ Very much
14. Have you ever been told by a health care provider that you have high blood sugar or diabetes? _____No _____Yes **<u>If you answered yes</u>**, please answer the question on the right.	How much does this health problem affect your current daily life? (Check **<u>one</u>**.) ☐ Not at all ☐ A little ☐ Somewhat ☐ Quite a bit ☐ Very much
15. Have you ever been told by a health care provider that you have kidney trouble? _____No _____Yes **<u>If you answered yes</u>**, please answer the question on the right.	How much does this health problem affect your current daily life? (Check **<u>one</u>**.) ☐ Not at all ☐ A little ☐ Somewhat ☐ Quite a bit ☐ Very much

16. Over the past year, have you had a problem with urine leaking out before or after you go to the bathroom? _____No _____Yes **If you answered yes**, please answer the question on the right.	How much does this health problem affect your current daily life? (Check **one**.) ☐ Not at all ☐ A little ☐ Somewhat ☐ Quite a bit ☐ Very much
17. Have you ever been told by a health care provider that you have a thyroid problem? _____No _____Yes **If you answered yes**, please answer the question on the right.	How much does this health problem affect your current daily life? (Check **one**.) ☐ Not at all ☐ A little ☐ Somewhat ☐ Quite a bit ☐ Very much
18. Have you ever been told by a health care provider that you have one or more different types of cancer (not cancer that has spread to another place in the body)? _____No _____Yes **If you answered yes**, please answer the question on the right.	How much does this health problem affect your current daily life? (Check **one**.) ☐ Not at all ☐ A little ☐ Somewhat ☐ Quite a bit ☐ Very much
19. Have you ever been told by a health care provider that you have arthritis? _____No _____Yes **If you answered yes**, please answer the question on the right.	How much does this health problem affect your current daily life? (Check **one**.) ☐ Not at all ☐ A little ☐ Somewhat ☐ Quite a bit ☐ Very much
20. Have you ever been told by a health care provider that you have osteoporosis, weakened bones, bone loss, or broken bones? _____No _____Yes **If you answered yes**, please answer the question on the right.	How much does this health problem affect your current daily life? (Check **one**.) ☐ Not at all ☐ A little ☐ Somewhat ☐ Quite a bit ☐ Very much

21. Have you ever had a knee or hip replacement? _____No _____Yes **<u>If you answered yes</u>**, please answer the question on the right.	How much does this health problem affect your current daily life? (Check **<u>one</u>**.) ☐ Not at all ☐ A little ☐ Somewhat ☐ Quite a bit ☐ Very much
22. Have you ever been overweight by 50 pounds or more? _____No _____Yes **<u>If you answered yes</u>**, please answer the question on the right.	How much does this health problem affect your current daily life? (Check **<u>one</u>**.) ☐ Not at all ☐ A little ☐ Somewhat ☐ Quite a bit ☐ Very much
23. Over the past year, have you had problems with your balance that has caused you to trip or fall? _____No _____Yes **<u>If you answered yes</u>**, please answer the question on the right.	How much does this health problem affect your current daily life? (Check **<u>one</u>**.) ☐ Not at all ☐ A little ☐ Somewhat ☐ Quite a bit ☐ Very much
24. Over the past year, have you walked with a shuffle or had trembling hands or other body parts most of the time? _____No _____Yes **<u>If you answered yes</u>**, please answer the question on the right.	How much does this health problem affect your current daily life? (Check **<u>one</u>**.) ☐ Not at all ☐ A little ☐ Somewhat ☐ Quite a bit ☐ Very much
25. Over the past year, have you had trouble remembering things? _____No _____Yes **<u>If you answered yes</u>**, please answer the question on the right.	How much does this health problem affect your current daily life? (Check **<u>one</u>**.) ☐ Not at all ☐ A little ☐ Somewhat ☐ Quite a bit ☐ Very much

26. Over the past year, have you had mixed up or confusing thoughts? _____No _____Yes **<u>If you answered yes</u>**, please answer the question on the right.	How much does this health problem affect your current daily life? (Check **<u>one</u>**.) ☐ Not at all ☐ A little ☐ Somewhat ☐ Quite a bit ☐ Very much
27. Over the past year, have you been diagnosed with and/ or treated for depression? _____No _____Yes **<u>If you answered yes</u>**, please answer the question on the right.	How much does this health problem affect your current daily life? (Check **<u>one</u>**.) ☐ Not at all ☐ A little ☐ Somewhat ☐ Quite a bit ☐ Very much
28. Over the past year, have you been diagnosed and/ or treated for anxiety or nervousness? _____No _____Yes **<u>If you answered yes</u>**, please answer the question on the right.	How much does this health problem affect your current daily life? (Check **<u>one</u>**.) ☐ Not at all ☐ A little ☐ Somewhat ☐ Quite a bit ☐ Very much
29. Over the past year, have you had any problems with your eyes that affect your general vision? _____No _____Yes **<u>If you answered yes</u>**, please answer the question on the right.	How much does this health problem affect your current daily life? (Check **<u>one</u>**.) ☐ Not at all ☐ A little ☐ Somewhat ☐ Quite a bit ☐ Very much
30. Over the past year, have you had any major changes in your hearing? _____No _____Yes **<u>If you answered yes</u>**, please answer the question on the right.	How much does this health problem affect your current daily life? (Check **<u>one</u>**.) ☐ Not at all ☐ A little ☐ Somewhat ☐ Quite a bit ☐ Very much

31. Over the past year, have you had any problems with bruising or bleeding problem that needed medication or some other treatment? _____No _____Yes **<u>If you answered yes</u>**, please answer the question on the right.	How much does this health problem affect your current daily life? (Check **<u>one</u>**.) ☐ Not at all ☐ A little ☐ Somewhat ☐ Quite a bit ☐ Very much
32. Over the past year, have you had anemia (a low red blood cell count)? _____No _____Yes **<u>If you answered yes</u>**, please answer the question on the right.	How much does this health problem affect your current daily life? (Check **<u>one</u>**.) ☐ Not at all ☐ A little ☐ Somewhat ☐ Quite a bit ☐ Very much
33. Over the past year, have you had any problems with your reproductive organs (such as prostate gland, uterus, or ovaries)? _____No _____Yes **<u>If you answered yes</u>**, please answer the question on the right.	How much does this health problem affect your current daily life? (Check **<u>one</u>**.) ☐ Not at all ☐ A little ☐ Somewhat ☐ Quite a bit ☐ Very much
34. If you have any other chronic illness or condition that has not been listed, please list below: _____No _____Yes **<u>If you answered yes</u>**, please list on the lines below. Please answer the question on the right. _____ _____ _____	How much do these health problems affect your current daily life? (Check **<u>one</u>**.) ☐ Not at all ☐ A little ☐ Somewhat ☐ Quite a bit ☐ Very much

*Please record the amount of time that it took for you complete this section:_____min.

Thank you for completing this section of the survey.

The next section of the survey continues on the next page.

Chronic Illness and Symptom Survey
Part 2

<u>Directions</u>:

This is a two-part survey which asks questions about your health, illnesses, and symptoms. Part Two asks questions about your symptoms.

Please read the survey carefully and answer all of the questions to the best of your ability. If you feel uncomfortable answering a question, skip that question and move on to the next question.

1. **During the past week**, have you had difficulty concentrating? _____No **If you answered no**, Please go to question 2. _____Yes **If you answered yes**, Please answer the questions in the next 2 columns →	1b. **How much does this symptom bother you?** [Please check one.] ☐ Not at all ☐ A little bit ☐ Somewhat ☐ Quite a bit ☐ Very much →	1c. **If you answered yes to the question about the symptom**, please answer the following question. Check **one** of the following statements that you think is true about your symptom of difficulty concentrating. ☐ The cause of this symptom is **mostly** age-related. ☐ The cause of this symptom is **mostly** related to my cancer and/ or cancer treatments. ☐ The cause of this symptom is **mostly** related to a non-cancer condition or treatment. ☐ This symptom has some other cause. (Write in what you think is causing the symptom.)
2. **During the past week**, have you had trouble remembering? _____No **If you answered no**, Please go to question 3. _____Yes **If you answered yes**, Please answer the questions in the next 2 columns →	2b. **How much does this symptom bother you?** [Please check one.] ☐ Not at all ☐ A little bit ☐ Somewhat ☐ Quite a bit ☐ Very much →	2c. **If you answered yes to the question about the symptom**, please answer the following question. Check **one** of the following statements that you think is true about your symptom of trouble remembering. ☐ The cause of this symptom is **mostly** age-related. ☐ The cause of this symptom is **mostly** related to my cancer and/ or cancer treatments. ☐ The cause of this symptom is **mostly** related to a non-cancer condition or treatment. ☐ This symptom has some other cause. (Write in what you think is causing the symptom.)

3. **During the past week**, have you had pain? _____No **If you answered no**, Please go to question 4. _____Yes **If you answered yes**, Please answer the questions in the next 2 columns →	3b. **How much does this symptom bother you?** [Please check one.] ☐ Not at all ☐ A little bit ☐ Somewhat ☐ Quite a bit ☐ Very much →	3c. **If you answered yes to the question about the symptom**, please answer the following question. Check **one** of the following statements that you think is true about your symptom of pain. ☐ The cause of this symptom is **mostly** age-related. ☐ The cause of this symptom is **mostly** related to my cancer and/ or cancer treatments. ☐ The cause of this symptom is **mostly** related to a non-cancer condition or treatment. ☐ This symptom has some other cause. (Write in what you think is causing the symptom.)
4. **During the past week**, have you had fatigue or lack of energy? _____No **If you answered no**, Please go to question 5. _____Yes **If you answered yes**, Please answer the questions in the next 2 columns →	4b. **How much does this symptom bother you?** [Please check one.] ☐ Not at all ☐ A little bit ☐ Somewhat ☐ Quite a bit ☐ Very much →	4c. **If you answered yes to the question about the symptom**, please answer the following question. Check **one** of the following statements that you think is true about your symptom of fatigue. ☐ The cause of this symptom is **mostly** age-related. ☐ The cause of this symptom is **mostly** related to my cancer and/ or cancer treatments. ☐ The cause of this symptom is **mostly** related to a non-cancer condition or treatment. ☐ This symptom has some other cause. (Write in what you think is causing the symptom.)

5. **During the past week**, have you had a cough? _____No **If you answered no**, Please go to question 6. _____Yes **If you answered yes**, Please answer the questions in the next 2 columns →	5b. **How much does this symptom bother you?** [Please check one.] ☐ Not at all ☐ A little bit ☐ Somewhat ☐ Quite a bit ☐ Very much →	5c. **If you answered yes to the question about the symptom**, please answer the following question. Check **one** of the following statements that you think is true about your symptom of a cough. ☐ The cause of this symptom is **mostly** age-related. ☐ The cause of this symptom is **mostly** related to my cancer and/ or cancer treatments. ☐ The cause of this symptom is **mostly** related to a non-cancer condition or treatment. ☐ This symptom has some other cause. (Write in what you think is causing the symptom.)
6. **During the past week**, have you had skin changes (such as altered skin color, thin or fragile skin, reddened skin or rash)? _____No **If you answered no**, Please go to question 7. _____Yes **If you answered yes**, Please answer the questions in the next 2 columns →	6b. **How much does this symptom bother you?** [Please check one.] ☐ Not at all ☐ A little bit ☐ Somewhat ☐ Quite a bit ☐ Very much →	6c. **If you answered yes to the question about the symptom**, please answer the following question. Check **one** of the following statements that you think is true about your symptom of skin changes. ☐ The cause of this symptom is **mostly** age-related. ☐ The cause of this symptom is **mostly** related to my cancer and/ or cancer treatments. ☐ The cause of this symptom is **mostly** related to a non-cancer condition or treatment. ☐ This symptom has some other cause. (Write in what you think is causing the symptom.)

7. **During the past week**, have you had a dry mouth? _____No **If you answered no**, Please go to question 8. _____Yes **If you answered yes**, Please answer the questions in the next 2 columns →	7b. **How much does this symptom bother you?** [Please check one.] □ Not at all □ A little bit □ Somewhat □ Quite a bit □ Very much →	7c. **If you answered yes to the question about the symptom**, please answer the following question. Check **one** of the following statements that you think is true about your symptom of dry mouth. □ The cause of this symptom is **mostly** age-related. □ The cause of this symptom is **mostly** related to my cancer and/ or cancer treatments. □ The cause of this symptom is **mostly** related to a non-cancer condition or treatment. □ This symptom has some other cause. (Write in what you think is causing the symptom.)
8. **During the past week**, have you had nausea? _____No **If you answered no**, Please go to question 9. _____Yes **If you answered yes**, Please answer the questions in the next 2 columns →	8b. **How much does this symptom bother you?** [Please check one.] □ Not at all □ A little bit □ Somewhat □ Quite a bit □ Very much →	8c. **If you answered yes to the question about the symptom**, please answer the following question. Check **one** of the following statements that you think is true about your symptom of nausea. □ The cause of this symptom is **mostly** age-related. □ The cause of this symptom is **mostly** related to my cancer and/ or cancer treatments. □ The cause of this symptom is **mostly** related to a non-cancer condition or treatment. □ This symptom has some other cause. (Write in what you think is causing the symptom.)

9. **During the past week**, have you had vomiting? _____No **If you answered no**, Please go to question 10. _____Yes **If you answered yes**, Please answer the questions in the next 2 columns →	9b. **How much does this symptom bother you?** [Please check one.] ☐ Not at all ☐ A little bit ☐ Somewhat ☐ Quite a bit ☐ Very much →	9c. **If you answered yes to the question about the symptom**, please answer the following question. Check **one** of the following statements that you think is true about your symptom of vomiting. ☐ The cause of this symptom is **mostly** age-related. ☐ The cause of this symptom is **mostly** related to my cancer and/ or cancer treatments. ☐ The cause of this symptom is **mostly** related to a non-cancer condition or treatment. ☐ This symptom has some other cause. (Write in what you think is causing the symptom.)
10. **During the past week**, have you had a feeling of being drowsy? _____No **If you answered no**, Please go to question 11. _____Yes **If you answered yes**, Please answer the questions in the next 2 columns →	10b. **How much does this symptom bother you?** [Please check one.] ☐ Not at all ☐ A little bit ☐ Somewhat ☐ Quite a bit ☐ Very much →	10c. **If you answered yes to the question about the symptom**, please answer the following question. Check **one** of the following statements that you think is true about your symptom of being drowsy. ☐ The cause of this symptom is **mostly** age-related. ☐ The cause of this symptom is **mostly** related to my cancer and/ or cancer treatments. ☐ The cause of this symptom is **mostly** related to a non-cancer condition or treatment. ☐ This symptom has some other cause. (Write in what you think is causing the symptom.)

11. **During the past week**, have you had numbness/ tingling in hands or feet? _____No **If you answered no**, Please go to question 12. _____Yes **If you answered yes**, Please answer the questions in the next 2 columns →	11b. **How much does this symptom bother you?** [Please check one.] ☐ Not at all ☐ A little bit ☐ Somewhat ☐ Quite a bit ☐ Very much	11c. **If you answered yes to the question about the symptom**, please answer the following question. Check **one** of the following statements that you think is true about your symptom of numbness/ tingling in hands or feet. ☐ The cause of this symptom is **mostly** age-related. ☐ The cause of this symptom is **mostly** related to my cancer and/ or cancer treatments. ☐ The cause of this symptom is **mostly** related to a non-cancer condition or treatment. ☐ This symptom has some other cause. (Write in what you think is causing the symptom.)
12. **During the past week**, have you had difficulty sleeping? _____No **If you answered no**, Please go to question 13. _____Yes **If you answered yes**, Please answer the questions in the next 2 columns →	**12b. How much does this symptom bother you?** [Please check one.] ☐ Not at all ☐ A little bit ☐ Somewhat ☐ Quite a bit ☐ Very much	12c. **If you answered yes to the question about the symptom**, please answer the following question. Check **one** of the following statements that you think is true about your symptom of difficulty sleeping. ☐ The cause of this symptom is **mostly** age-related. ☐ The cause of this symptom is **mostly** related to my cancer and/ or cancer treatments. ☐ The cause of this symptom is **mostly** related to a non-cancer condition or treatment. ☐ This symptom has some other cause. (Write in what you think is causing the symptom.)

13. **During the past week**, have you had a feeling of being bloated? _____No **If you answered no**, Please go to question 14. _____Yes **If you answered yes**, Please answer the questions in the next 2 columns →	13b. **How much does this symptom bother you?** [Please check one.] ☐ Not at all ☐ A little bit ☐ Somewhat ☐ Quite a bit ☐ Very much →	13c. **If you answered yes to the question about the symptom**, please answer the following question. Check **one** of the following statements that you think is true about your symptom of being bloated. ☐ The cause of this symptom is **mostly** age-related. ☐ The cause of this symptom is **mostly** related to my cancer and/ or cancer treatments. ☐ The cause of this symptom is **mostly** related to a non-cancer condition or treatment. ☐ This symptom has some other cause. (Write in what you think is causing the symptom.)
14. **During the past week**, have you had urinary problems (such as going often, pain, leaking)? _____No **If you answered no**, Please go to question 15. _____Yes **If you answered yes**, Please answer the questions in the next 2 columns →	14b. **How much does this symptom bother you?** [Please check one.] ☐ Not at all ☐ A little bit ☐ Somewhat ☐ Quite a bit ☐ Very much →	14c. **If you answered yes to the question about the symptom**, please answer the following question. Check **one** of the following statements that you think is true about your symptom of urinary problems. ☐ The cause of this symptom is **mostly** age-related. ☐ The cause of this symptom is **mostly** related to my cancer and/ or cancer treatments. ☐ The cause of this symptom is **mostly** related to a non-cancer condition or treatment. ☐ This symptom has some other cause. (Write in what you think is causing the symptom.)

15. **During the past week**, have you had shortness of breath? _____No **If you answered no**, Please go to question 16. _____Yes **If you answered yes**, Please answer the questions in the next 2 columns →	15b. **How much does this symptom bother you?** [Please check one.] ☐ Not at all ☐ A little bit ☐ Somewhat ☐ Quite a bit ☐ Very much →	15c. **If you answered yes to the question about the symptom**, please answer the following question. Check **one** of the following statements that you think is true about your symptom of shortness of breath. ☐ The cause of this symptom is **mostly** age-related. ☐ The cause of this symptom is **mostly** related to my cancer and/ or cancer treatments. ☐ The cause of this symptom is **mostly** related to a non-cancer condition or treatment. ☐ This symptom has some other cause. (Write in what you think is causing the symptom.)
16. **During the past week**, have you had sweating which is not normal for you? _____No **If you answered no**, Please go to question 17. _____Yes **If you answered yes**, Please answer the questions in the next 2 columns →	16b. **How much does this symptom bother you?** [Please check one.] ☐ Not at all ☐ A little bit ☐ Somewhat ☐ Quite a bit ☐ Very much →	16c. **If you answered yes to the question about the symptom**, please answer the following question. Check **one** of the following statements that you think is true about your symptom of sweating. ☐ The cause of this symptom is **mostly** age-related. ☐ The cause of this symptom is **mostly** related to my cancer and/ or cancer treatments. ☐ The cause of this symptom is **mostly** related to a non-cancer condition or treatment. ☐ This symptom has some other cause. (Write in what you think is causing the symptom.)

17. **During the past week**, have you had hot flashes or hot flushes? _____No **If you answered no**, Please go to question 18. _____Yes **If you answered yes**, Please answer the questions in the next 2 columns →	17b. **How much does this symptom bother you?** [Please check one.] ☐ Not at all ☐ A little bit ☐ Somewhat ☐ Quite a bit ☐ Very much →	17c. **If you answered yes to the question about the symptom**, please answer the following question. Check **one** of the following statements that you think is true about your symptom of hot flashes. ☐ The cause of this symptom is **mostly** age-related. ☐ The cause of this symptom is **mostly** related to my cancer and/ or cancer treatments. ☐ The cause of this symptom is **mostly** related to a non-cancer condition or treatment. ☐ This symptom has some other cause. (Write in what you think is causing the symptom.)
18. **During the past week**, have you had problems with sexual interest or activity? _____No **If you answered no**, Please go to question 19. _____Yes **If you answered yes**, Please answer the questions in the next 2 columns →	18b. **How much does this symptom bother you?** [Please check one.] ☐ Not at all ☐ A little bit ☐ Somewhat ☐ Quite a bit ☐ Very much →	18c. **If you answered yes to the question about the symptom**, please answer the following question. Check **one** of the following statements that you think is true about your symptom of problems with sexual interest. ☐ The cause of this symptom is **mostly** age-related. ☐ The cause of this symptom is **mostly** related to my cancer and/ or cancer treatments. ☐ The cause of this symptom is **mostly** related to a non-cancer condition or treatment. ☐ This symptom has some other cause. (Write in what you think is causing the symptom.)

19. **During the past week**, have you had itching? _____No **If you answered no**, Please go to question 20. _____Yes **If you answered yes**, Please answer the questions in the next 2 columns →	19b. **How much does this symptom bother you?** [Please check one.] ☐ Not at all ☐ A little bit ☐ Somewhat ☐ Quite a bit ☐ Very much →	19c. **If you answered yes to the question about the symptom**, please answer the following question. Check **one** of the following statements that you think is true about your symptom of itching. ☐ The cause of this symptom is **mostly** age-related. ☐ The cause of this symptom is **mostly** related to my cancer and/ or cancer treatments. ☐ The cause of this symptom is **mostly** related to a non-cancer condition or treatment. ☐ This symptom has some other cause. (Write in what you think is causing the symptom.)
20. **During the past week**, have you had a lack of appetite? _____No **If you answered no**, Please go to question 21. _____Yes **If you answered yes**, Please answer the questions in the next 2 columns →	20b. **How much does this symptom bother you?** [Please check one.] ☐ Not at all ☐ A little bit ☐ Somewhat ☐ Quite a bit ☐ Very much →	20c. **If you answered yes to the question about the symptom**, please answer the following question. Check **one** of the following statements that you think is true about your symptom of lack of appetite. ☐ The cause of this symptom is **mostly** age-related. ☐ The cause of this symptom is **mostly** related to my cancer and/ or cancer treatments. ☐ The cause of this symptom is **mostly** related to a non-cancer condition or treatment. ☐ This symptom has some other cause. (Write in what you think is causing the symptom.)

21. **During the past week**, have you had dizziness? _____No **If you answered no**, Please go to question 22. _____Yes **If you answered yes**, Please answer the questions in the next 2 columns →	21b. **How much does this symptom bother you?** [Please check one.] ☐ Not at all ☐ A little bit ☐ Somewhat ☐ Quite a bit ☐ Very much →	21c. **If you answered yes to the question about the symptom**, please answer the following question. Check **one** of the following statements that you think is true about your symptom of dizziness. ☐ The cause of this symptom is **mostly** age-related. ☐ The cause of this symptom is **mostly** related to my cancer and/ or cancer treatments. ☐ The cause of this symptom is **mostly** related to a non-cancer condition or treatment. ☐ This symptom has some other cause. (Write in what you think is causing the symptom.)
22. **During the past week**, have you had difficulty swallowing? _____No **If you answered no**, Please go to question 23. _____Yes **If you answered yes**, Please answer the questions in the next 2 columns →	22b. **How much does this symptom bother you?** [Please check one.] ☐ Not at all ☐ A little bit ☐ Somewhat ☐ Quite a bit ☐ Very much →	22c. **If you answered yes to the question about the symptom**, please answer the following question. Check **one** of the following statements that you think is true about your symptom of difficulty swallowing. ☐ The cause of this symptom is **mostly** age-related. ☐ The cause of this symptom is **mostly** related to my cancer and/ or cancer treatments. ☐ The cause of this symptom is **mostly** related to a non-cancer condition or treatment. ☐ This symptom has some other cause. (Write in what you think is causing the symptom.)

23. **During the past week**, have you had mouth sores? _____No **If you answered no**, Please go to question 24. _____Yes **If you answered yes**, Please answer the questions in the next 2 columns →	23b. **How much does this symptom bother you?** [Please check one.] ☐ Not at all ☐ A little bit ☐ Somewhat ☐ Quite a bit ☐ Very much →	23c. **If you answered yes to the question about the symptom**, please answer the following question. Check **one** of the following statements that you think is true about your symptom of mouth sores. ☐ The cause of this symptom is **mostly** age-related. ☐ The cause of this symptom is **mostly** related to my cancer and/ or cancer treatments. ☐ The cause of this symptom is **mostly** related to a non-cancer condition or treatment. ☐ This symptom has some other cause. (Write in what you think is causing the symptom.)
24. **During the past week**, have you had changes in the way food tastes? _____No **If you answered no**, Please go to question 25. _____Yes **If you answered yes**, Please answer the questions in the next 2 columns →	24b. **How much does this symptom bother you?** [Please check one.] ☐ Not at all ☐ A little bit ☐ Somewhat ☐ Quite a bit ☐ Very much →	24c. **If you answered yes to the question about the symptom**, please answer the following question. Check **one** of the following statements that you think is true about your symptom of taste changes. ☐ The cause of this symptom is **mostly** age-related. ☐ The cause of this symptom is **mostly** related to my cancer and/ or cancer treatments. ☐ The cause of this symptom is **mostly** related to a non-cancer condition or treatment. ☐ This symptom has some other cause. (Write in what you think is causing the symptom.)

25. **During the past week**, have you had unexpected weight loss? _____No **If you answered no**, Please go to question 26. _____Yes **If you answered yes**, Please answer the questions in the next 2 columns →	25b. **How much does this symptom bother you?** [Please check one.] ☐ Not at all ☐ A little bit ☐ Somewhat ☐ Quite a bit ☐ Very much →	25c. **If you answered yes to the question about the symptom**, please answer the following question. Check **one** of the following statements that you think is true about your symptom of unexpected weight loss. ☐ The cause of this symptom is **mostly** age-related. ☐ The cause of this symptom is **mostly** related to my cancer and/ or cancer treatments. ☐ The cause of this symptom is **mostly** related to a non-cancer condition or treatment. ☐ This symptom has some other cause. (Write in what you think is causing the symptom.)
26. **During the past week**, have you had hair loss? _____No **If you answered no**, Please go to question 27. _____Yes **If you answered yes**, Please answer the questions in the next 2 columns →	26b. **How much does this symptom bother you?** [Please check one.] ☐ Not at all ☐ A little bit ☐ Somewhat ☐ Quite a bit ☐ Very much →	26c. **If you answered yes to the question about the symptom**, please answer the following question. Check **one** of the following statements that you think is true about your symptom of hair loss. ☐ The cause of this symptom is **mostly** age-related. ☐ The cause of this symptom is **mostly** related to my cancer and/ or cancer treatments. ☐ The cause of this symptom is **mostly** related to a non-cancer condition or treatment. ☐ This symptom has some other cause. (Write in what you think is causing the symptom.)

27. **During the past week**, have you had constipation? _____No **If you answered no**, Please go to question 28. _____Yes **If you answered yes**, Please answer the questions in the next 2 columns →	27b. **How much does this symptom bother you?** [Please check one.] ☐ Not at all ☐ A little bit ☐ Somewhat ☐ Quite a bit ☐ Very much →	27c. **If you answered yes to the question about the symptom**, please answer the following question. Check **one** of the following statements that you think is true about your symptom of constipation. ☐ The cause of this symptom is **mostly** age-related. ☐ The cause of this symptom is **mostly** related to my cancer and/ or cancer treatments. ☐ The cause of this symptom is **mostly** related to a non-cancer condition or treatment. ☐ This symptom has some other cause. (Write in what you think is causing the symptom.)
28. **During the past week**, have you had diarrhea? _____No **If you answered no**, Please go to question 29. _____Yes **If you answered yes**, Please answer the questions in the next 2 columns →	28b. **How much does this symptom bother you?** [Please check one.] ☐ Not at all ☐ A little bit ☐ Somewhat ☐ Quite a bit ☐ Very much →	28c. **If you answered yes to the question about the symptom**, please answer the following question. Check **one** of the following statements that you think is true about your symptom of diarrhea. ☐ The cause of this symptom is **mostly** age-related. ☐ The cause of this symptom is **mostly** related to my cancer and/ or cancer treatments. ☐ The cause of this symptom is **mostly** related to a non-cancer condition or treatment. ☐ This symptom has some other cause. (Write in what you think is causing the symptom.)

29. **During the past week**, have you had a feeling that "I don't look like myself"? _____No **If you answered no**, Please go to question 30. _____Yes **If you answered yes**, Please answer the questions in the next 2 columns →	29b. **How much does this symptom bother you?** [Please check one.] ☐ Not at all ☐ A little bit ☐ Somewhat ☐ Quite a bit ☐ Very much	29c. **If you answered yes to the question about the symptom**, please answer the following question. Check **one** of the following statements that you think is true about your symptom of feeling "I don't look like myself". ☐ The cause of this symptom is **mostly** age-related. ☐ The cause of this symptom is **mostly** related to my cancer and/ or cancer treatments. ☐ The cause of this symptom is **mostly** related to a non-cancer condition or treatment. ☐ This symptom has some other cause. (Write in what you think is causing the symptom.)
30. **During the past week**, have you worried, anxious, or nervous? _____No **If you answered no**, Please go to question 31. _____Yes **If you answered yes**, Please answer the questions in the next 2 columns →	30b. **How much does this symptom bother you?** [Please check one.] ☐ Not at all ☐ A little bit ☐ Somewhat ☐ Quite a bit ☐ Very much	30c. **If you answered yes to the question about the symptom**, please answer the following question. Check **one** of the following statements that you think is true about your symptom of being nervous or anxious. ☐ The cause of this symptom is **mostly** age-related. ☐ The cause of this symptom is **mostly** related to my cancer and/ or cancer treatments. ☐ The cause of this symptom is **mostly** related to a non-cancer condition or treatment. ☐ This symptom has some other cause. (Write in what you think is causing the symptom.)

31. **During the past week**, have you had a feeling of being irritable? _____No **If you answered no**, Please go to question 32. _____Yes **If you answered yes**, Please answer the questions in the next 2 columns →	31b. **How much does this symptom bother you?** [Please check one.] ☐ Not at all ☐ A little bit ☐ Somewhat ☐ Quite a bit ☐ Very much →	31c. **If you answered yes to the question about the symptom**, please answer the following question. Check **one** of the following statements that you think is true about your symptom of feeling irritable. ☐ The cause of this symptom is **mostly** age-related. ☐ The cause of this symptom is **mostly** related to my cancer and/ or cancer treatments. ☐ The cause of this symptom is **mostly** related to a non-cancer condition or treatment. ☐ This symptom has some other cause. (Write in what you think is causing the symptom.)
32. **During the past week**, have you had a feeling of being sad or blue? _____No **If you answered no**, Please go to question 33. _____Yes **If you answered yes**, Please answer the questions in the next 2 columns →	32b. **How much does this symptom bother you?** [Please check one.] ☐ Not at all ☐ A little bit ☐ Somewhat ☐ Quite a bit ☐ Very much →	32c. **If you answered yes to the question about the symptom**, please answer the following question. Check **one** of the following statements that you think is true about your symptom of feeling sad. ☐ The cause of this symptom is **mostly** age-related. ☐ The cause of this symptom is **mostly** related to my cancer and/ or cancer treatments. ☐ The cause of this symptom is **mostly** related to a non-cancer condition or treatment. ☐ This symptom has some other cause. (Write in what you think is causing the symptom.)

33. **During the past week**, have you had other symptoms not listed in this survey? _____No _____Yes Please list other symptoms: **If you answered yes**, Please answer the questions in the next 2 columns →	33b. **How much does this symptom bother you?** [Please check one.] □ Not at all □ A little bit □ Somewhat □ Quite a bit □ Very much →	33c. **If you answered yes to the question about the symptom**, please answer the following question. Check **one** of the following statements that you think is true about your symptom. □ The cause of this symptom is **mostly** age-related. □ The cause of this symptom is **mostly** related to my cancer and/ or cancer treatments. □ The cause of this symptom is **mostly** related to a non-cancer condition or treatment. □ This symptom has some other cause. (Write in what you think is causing the symptom.)

Thank you for your time in completing this survey.